Veterinary Handbook for Herd Management in the bovine TB eradication programme

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The assistance of all who have helped compile this manual is acknowledged and much appreciated.
1. Introduction

The Bovine TB Eradication Scheme commenced in 1954 using the Single Intradermal Comparative Tuberculin Test (SICCT). Before the scheme started it was common to find, ‘piner’ animals, with clinical tuberculosis, cows with TB mastitis excreting *Mycobacterium bovis* in milk, as well as carcasses condemned with generalised TB. Many families had members suffering from TB and in 1952, the recorded rate of TB notifications in Ireland was 230/100,000 population. Initially, the incidence of TB in cattle was about 17% overall (and in cows as high as 22%). In the first 10 years of the scheme, some 800,000 TB reactors were slaughtered from a cattle population of circa 5 million head. By 1964 the position had improved significantly and that year, just 0.75% of the national herd of 5,659,344, or some 40,433 animals were TB reactors, which represented a 23-fold reduction in reactor numbers. In October 1965, Charles Haughey T.D. the then Minister for Agriculture announced “To mark this memorable occasion of the formal declaration of the whole state as cleared of bovine tuberculosis, I thought it well to publish a complete account of how the job was done” and he proceeded to do so’. In hindsight we know that this declaration was somewhat premature!

Ireland complies fully with EU Directive 64/432/EEC, commonly known as the trade Directive. It was doing so even before joining the EU (then the EEC) in order to facilitate trade in bovine animals from Ireland. However, compliance with this Directive is not sufficient to ensure the eradicating of TB in bovines which is the objective of the current Irish bovine TB (bTB) eradication programme, (latest version submitted to EU is to be found on DAFM’s website) and hence, the necessity to implement additional measures beyond the terms of the trade Directive. In addition, Ireland conforms to the stipulations of Directives 77/391 and 78/52 as is mandatory for an EU approved bTB eradication programme and for co-funding of the programme by the EU.

In the autumn of 1988 the first version of the ‘Categorisation document’ was circulated. This set out a strategic response to the management of herd restrictions. It defined herds in terms of the severity of the disease outbreak and provided for additional measures, to be employed where it was felt that these were warranted thereby providing for a more targeted use of resources. At around the same period it was recognised that significant constraints existed in relation to TB eradication. Many of these constraints have been identified subsequently. The most significant is the presence of *M. bovis* in wildlife reservoir hosts namely the badger (*Meles meles*) and to a lesser extent the wild deer population. (In Ireland TB, due to *M. bovis*, was first reported, in badgers from West Cork, in 1975). The identification and alleviation of these constraints has been, and continues to be, the focus of considerable research funded by DAFM. The ‘Handbook for the Management of herds under restriction for Tuberculosis’ replaced the initial ‘Categorisation Document’ and is revised periodically in order to reflect the scientifically informed changes in this Department’s policy with regard to the management of tuberculosis-restricted herds. It is intended that this manual will reflect current policy by means of regular reviews and consequent updates.

In Ireland, science and policy are closely linked for the benefit of the Irish bTB eradication programme, with scientists addressing the what (what are the key factors that influence bTB risk, locally, in herds, among animals?) and the why (what is the biological basis behind the observations?) and policy-makers considering the how (how are observed risks and findings best managed?). The research draws on both in-house expertise in veterinary epidemiology, database management, geographic information systems and statistics and also a broad portfolio of research projects. Three research groups in particular, each based within the University College Dublin School of Veterinary Medicine, including the Centre for Veterinary Epidemiology and Risk Analysis, the TB Diagnostics and Immunology Research Centre, and the Badger Vaccine Project have provided substantial contributions to policy development since the late 1980s. The eradication programme is built on a twin-track approach to tackling the disease – systematically addressing both bovine-to-bovine spread as well as the wildlife to bovine cycle. It incorporates conventional disease control strategies appropriate to a domesticated animal species i.e. test, slaughter, disinfect, test in-contact/associated herds, trace at risk animals and the restriction of in/out movement. In addition the programme also incorporates measures designed to reduce the badger population in areas where they are seen to be, or to have been, contributing to bovine TB prevalence while a BCG based vaccine for TB in badgers is in development and under trial. To date, the contribution, if any, made by wild deer to TB in

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cattle has not been fully clarified although, studies are ongoing. Deer hunters have been trained to assess carcasses for human consumption by or on behalf of the FSAI. On occasion these hunters submit abnormal findings to the laboratory for examination and thus TB is detected. However, Wicklow is unique in consistently each year submitting TB positive samples from deer to DAFM for examination. See Section 18 for further details.

In summary, the measures in the programme include
- identification of individual herds as the epidemiological unit of relevance for the purpose of disease control;
- an annual round screening test of all herds;
- individual animal identification;
- controls on movement of animals;
- restriction of holdings where bTB is suspected or confirmed;
- removal and slaughter of reactors;
- disinfection;
- specific targeted testing, including the use of blood tests, with appropriate follow-up testing;
- compensation for farmers whose herds are affected by disease;
- a focused badger population control where they have been implicated as a probable cause of bTB and
- continued work towards the development and introduction of a vaccine to control TB in badgers so as to effectively deal with a disease that moves between domestic and wild animal populations.

Bovine TB has been eradicated in Australia and to a very significant degree in New Zealand. Both countries experienced a problem with wildlife infection that was dealt with by the widespread and systematic destruction of the wildlife reservoir. While it is acknowledged that eliminating badgers in Ireland would probably result in a more successful cattle tuberculosis eradication scheme, such a policy would be unacceptable at a number of levels. At the societal level, the destruction of one of our important native large species of mammal would be completely unthinkable. In addition, the EU is a signatory of the 1989 Convention on the Conservation of European Wildlife and Natural Habitats (Berne Convention), and the Irish government ratified this treaty in 1982. Under Irish Law (The Wildlife Act, 1976), the Eurasian badger (M. meles) is a protected species. This includes protection of the underground burrows (setts) where badgers live and breed their young. Research conducted over the years by DAFM and others, however, demonstrated that the eradication of bTB is not a practicable proposition until the issue of the reservoir of infection in badgers seeding infection into the cattle population, is addressed. Therefore, in 2000, a badger population reduction strategy was introduced², which involves the removal of badgers when an epidemiological investigation carried out by the Department’s Veterinary Inspectorate associates a serious outbreak of TB in cattle with the presence of badgers. The Department of Arts, Heritage and the Gaeltacht, specifically the National Parks and Wildlife Service, issues licences to the Department of Agriculture, Food and the Marine to undertake the capturing programme. Approval to capture at a sett is contingent on the total area under capture nationally being maintained below 30% of the agricultural land in the country. Approximately 6,000 badgers have been removed annually under the wildlife programme in recent years. Badgers are removed for post-mortem assessment and examination with respect to welfare, wounds, pregnancy; lactation etc. and a standard set of samples are taken for (pooled) culture for TB and the badger carcasses disposed of in a licensed rendering plant. The badger population density control has resulted in an overall decline in mean prevalence of TB within culled badger populations from 26% in 2007 to 11% in 2011³. This policy is not universally accepted but the Council of Europe has rejected a complaint from the Irish Wildlife Trust regarding the threat to the badger population posed by the Department’s badger culling policy. The Council noted Ireland’s badger population is not being threatened and that badger numbers are being maintained at safe but lower levels.

The Department continues to invest in extensive research to study badger ecology and develop a TB vaccination programme for badgers. The objective of the research is to replace badger culling with vaccination when research demonstrates that this is a practicable proposition. As the disease level reduces

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in badgers the need to remove infected social groups will diminish. Currently the disease level in badgers appears to be less than half of what it had been in 2002. The Department and the research team have been collaborating for some years with Government and relevant agencies in the UK, and more recently in France, on vaccine development to control tuberculosis in badgers and to break the link of infection to cattle. Research has demonstrated that oral vaccination of badgers, with the BCG vaccine, in a captive environment generates high levels of protective immunity against challenge with M. bovis. Field trials have been and are also being undertaken in several Counties, involving vaccination, with oral and injectable vaccines, of several hundred badgers over 3 to 4 years, with continuous monitoring of the population to assess the impact of the vaccine on the incidence of disease both in the vaccinated and non-vaccinated control badger populations and also in the cattle population. The field work for the first of these trials (Kilkenny with oral BCG vaccine) is completed. The Kilkenny vaccine trial set out to test the efficacy of oral BCG vaccination against natural infection of free-living badgers over a wide geographic area. Up to 1,000 badgers were recruited to the study and allocated to different zones, whereby they were vaccinated with BCG or placebo. Treatment of badgers continued for three years. The outcome of interest was incident cases of tuberculosis as measured by serological responses and severity of disease at post-mortem. The report and the report of findings and outcomes of the Kilkenny vaccine trial are expected in 2016/17. Preliminary analysis indicates a positive outcome of the trial with a decrease in serologically positive badgers and clinical disease levels in zones with 100% oral vaccination. Success in the field trials will it is hoped, eventually lead to implementation of a vaccination strategy, hopefully with an oral vaccine, most likely in combination with some culling, as part of the national bTB control programme. Since it will be some years before the benefits of a vaccine can be seen in the wider population, the targeted removal of infected badger social groupings will continue in the medium term while increasingly it is anticipated that oral vaccine will be deployed to protect the surrounding unexposed populations.

Very considerable progress was made in the early years of the bTB eradication programmes and there has also been a progressive reduction, with some annual variations, in the level of the disease since 1998 particularly regarding reactor numbers which fell from c.45,000 to 15,317 in 2015. In 2011, for the first time since the nationwide compulsory test and cull programme for bovines began 60 years ago, and despite the increase in bovine population by some 2 million head, reactor numbers fell below 20,000 to 18,531. The average number of reactors removed in the 5-year period 2011-15 was 16,816, 33% lower than the 25,160 average removed in the preceding 5-year period (2006-10), despite additional use of blood tests, stricter test interpretation in infected herds, particularly in cohorts within infected groups and consequent removal of increasing numbers of reactor animals disclosed during a herd breakdown. Indeed in 2015 the number of reactor animals removed was 66% lower than in 1999. The herd incidence continues to fall and, during the same period, has fallen from 7.7% in 1999 to 3.37% in 2015. Research also indicates that the rate of repeat breakdown in herds has also reduced. While there has been considerable emphasis on greater attention to detail and enhanced quality control over the period and though it is difficult to quantify the precise impact of badger culling on the incidence of TB in Ireland over the past 10 years or so, the Department believes that much of this improvement is due to the strategic removal of diseased badger social groups. A 2014 study revisited the ‘four area project’ areas to assess if there were any residual area effects of this former badger removal intervention a decade later (2007-12). Over the study period there was an overall declining trend in bTB breakdown risk to cattle herds. However, cattle herds within former removal areas experienced significantly reduced risk of breakdown relative to herds within former reference areas or herds within non-treatment areas (OR: 0.53; P <0.001) thus demonstrating the long term effect of badger removal. Recent analysis of data to end of 2015 has demonstrated that the target of bTB eradication by 2030 is a reasonable prospect if progress over the last 15-years is sustained and progress is made in making TB susceptibility/resistance a feature of the selection possibilities for bovine breeding.

The tuberculin used in the initial years of the eradication programme was prepared from strains of M. tuberculosis (i.e. the human strain of TB) and in 1978 this was changed to tuberculin prepared from M. bovis to improve both Sensitivity (Se) and Specificity (Sp) of the test. In the early 1980s the manufacturer of the current tuberculin won the supply contract and has continued to do so for each subsequent tender. Ireland uses tuberculin of higher potency (bovine 30,000LU/ml and avian 25,000LU/ml) than the minimum specified in the Directive (20,000I.U./ml for both avian and bovine PPDs) so as to optimise Se to achieve eradication while at the same time maintaining an acceptable Sp. The potency of the tuberculin

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supplied is regularly checked, at Central Veterinary Research Laboratory, against EU and Irish standards using cattle naturally infected with *M. bovis*.

There have been other major changes to the eradication programme. The concept of cost sharing was introduced, whereby the farmer pays the private veterinary practitioner directly for conducting one full herd test annually. The relevant Annexes to Directive 64/432/EEC have been amended and the current Annex A and Annex B are at Appendix 1 of this manual as is Directive 78/52/EEC. The resources available to the ERAD and Ruminant Animal Health, Identification and Traceability Divisions and our understanding of the underlying epidemiology of the disease have changed as scientific information and data analysis have become available. Much of the programme has been computerised since 1986. In 2005 a new integrated system – The Animal Health Computer System (AHCS) – was operational in all RVOs. PVPs and WTVIs rapidly adopted the system so that by 2016 in excess of 98% of tests done by PVPs/WTVIs are reported electronically. AHCS is integrated with the Animal Identification and Movement System (AIMS) and the Laboratory Information Management System (LIMS) so that slaughter plants and the CVRL now interact directly with AHCS. Linkage with AIM facilitates pre-clearance of animals to ensure eligibility before farm-to-farm movement, sale, entering the food chain or export. AHCS has also facilitated the development of a comprehensive test QC methodology that takes key performance indicators into consideration when assessing risk. The linkage with AIM also facilitates the identification of discrepancies between test records and the herd profile on the traceability (AIMS) database when each and every test is performed and to alert when non compliant moves are detected.

**Zoonotic Risk.**

Bovine TB is no longer the zoonotic threat that it was in the past. In 2015, 315 human cases of TB were notified in Ireland, giving a national crude incidence rate of 6.9/100,000 population. Almost 40% of these TB cases were born outside Ireland. Of the 197 (62.5%) culture-confirmed cases, 168 (85.3%) were *M. tuberculosis* and five (2.5%) were *M. bovis*. There is, however, evidence, directly from affected farmers, that some cases of human TB in recent years have been attributed to *M. bovis* and linked to severe TB outbreaks in Irish herds (P. Doran, paper 7 in appendix 9, T. Mac White and L. Meaney personal communication; Masters Thesis by James Casey poster paper 5 in appendix 9). *M. bovis* has inherently different culture requirements than *M. tuberculosis* and therefore *M. bovis* is not routinely cultured or isolated and consequently not recorded as the cause of human TB even in cases where lesion/gland biopsy (Doran case) or smear tests on pleural effusions (MacWhite case) have detected acid-fast bacteria, antimycobacterial therapy has been successful (Meaney case) and the epidemiology convincing (all of these). Care must always be taken to advise farmers, farm families and workers of the risk of zoonotic *M. bovis* infection particularly, but not exclusively, where raw milk is being consumed on farm and this is critical if there is evidence indicating calf infection by milk consumption. In addition it should be pointed out to the farmer, his family and the farm workers that chest X-Ray is often insufficient in the case of *M. bovis* exposure and either Mantu (skin test) or IGRA (Interferon Gamma Release Assay) is strongly advised as *M. bovis* has a history of being responsible for higher rates of extra-pulmonary TB. Prior to the introduction of pasteurisation of milk *M. bovis* in the 1930s in G.B, accounted for 1% of pulmonary TB and 30% of extra-pulmonary TB; however, it accounted for 68% of cases in children 5 years and younger. The introduction of compulsory pasteurisation, e.g. in Toronto in 1918 where TB as a reason to admit a child, born and raised in the city, to hospital disappeared, and in the Netherlands in 1940, led to a marked decline in TB. Pasteurisation also dramatically changed the profile of the anatomical presentation of human cases of TB and the once common Meningeal, bone, joint and skin TB in humans became rare. However, in GB pasteurisation only finally became compulsory after 1948 and meat inspection for TB didn’t become uniform till the 1950s. Thus in 1951 the rate of tuberculosis attributable to *M. bovis* was higher in Britain than in any other industrial nation.

In summary the current Irish bTB eradication programme has been shown to be fully capable of reducing and ultimately eradicating TB from cattle herds. However, the ability to eradicate tuberculosis from cattle at the national level is constrained while infection continues to spill over from badgers. The interim badger control programme, coupled with a comprehensive bTB eradication programme and superior IT tools, has facilitated significant progress in reducing infection levels in both species. Nevertheless, this is limited by the numbers of badgers that can be removed and the percentage of the agricultural land that can be subject to badger population controls. Ultimate success is dependent on further reducing the level of infection in the badger population and to achieve this vaccination, with continued culling in hot-spots, is the only strategic option available. Providing scientific support for the incorporation of BCG vaccination of badgers into the national bTB eradication programme is the objective of the badger research studies. As disease levels
progressively decline, the controls on infected herds and animals will necessarily become increasingly rigorous so as to prevent spread and/or recrudescence until eradication is finally achieved.

2. Herdnumbers

Since 1957 and the inception of the Bovine TB eradication programme in Ireland each single unique epidemiologically distinct herd is allocated a herdnumber for the purpose of disease control. A comprehensive circular, ERAD Circular 17 of 2010, dealing with all issues relating to herdnumbers, lists the relevant circulars on herdnumber issues and outlines procedures to be followed in all matters relating to herdnumbers, including the issue of additional herdnumbers to split holdings either operating different enterprises as distinct and separate epidemiological units or with fragments of the holding sufficiently distant to necessitate such numbers for disease control purposes. In addition circular ER 07/15 covers the trading and disease/health status requirements for newly established/reactivated dormant herds.

A herdnumber is an administrative system issued under the bovine disease eradication schemes for the purpose of individual herd identification of each epidemiological unit and the management of bovine animal identification and disease status certification under the various bovine disease testing programmes. Under SI 58/2015, the Animal Health And Welfare (Bovine Tuberculosis) Regulations 2015 an “epidemiological unit” means a number of animals (whether owned by the one person or otherwise) that are held, kept or handled in such a manner that they share the same likelihood of exposure to bovine tuberculosis and the control of the spread of infectious disease from the unit can be facilitated; It is a pre-requisite that each distinct epidemiological unit must be represented by one and ONLY one herdnumber. This principle is enshrined in law in SI 58/2015 (Appendix 1b).

Questions as to ownership of particular lands or animals are only of secondary importance, as a herdnumber does not denote ownership of stock or land and functions solely as a method of herd identification and control from a disease and animal traceability viewpoint. Thus the person, in whose name the herdnumber is registered, being the (nominated) keeper of the herd and of the animals located therein, may or may not be the legal owner of any of the animals held under that herdnumber or any of the lands/premises associated with that herd/herdnumber. The person registered as the keeper is recorded on DAFM’s Corporate Client System (CCS) in a non-payee role (i.e. no payments may be made to a person in a keeper role). An applicant herdowner’s position viz. a viz. eligibility for support payments or other schemes is not to be considered in assessing eligibility for a herdnumber. Accordingly, it is appropriate that consideration of eligibility of an application for a herdnumber (one or more to a person/group of persons/partnership/joint venture etc.) is reserved by DAFM as an SVI function. The SVI will also determine if/when herdnumbers should be amalgamated or cancelled while there is stock located in a herdnumber. Issues which

a) involve any change to the lands or farming system or

b) involve persons already on the CSS with an interest in another existing herdnumber,

must always be approved by the local SVI in the RVO.

Issues not covered by above two items (a) and (b) such as

i. the addition of, for example, a son, daughter or spouse to the list of persons with an interest in the herdowner role or

ii. the transfer of the herdowner role, to a successor, on the instruction of the persons currently in that role, or

iii. the reassignment of a herdnumber to a correct DED or

iv. end-dating or making dormant for testing purposes a herdnumber where there no longer is any stock e.g. when a farmer is deceased, or retiring,

are purely administrative tasks with no impact on disease or animal control. However, in processing such changes there should always be due regard to ensuring there are no livestock involved, no outstanding payments awaiting issue, existing, pending or potential controls or sanctions being investigated or processed, prosecutions, disallowances or similar, evasion of which may motivate changes in the herdowner role and thus appropriate checks should always be undertaken with the local RVO staff familiar with the actual locality in which the herd is situated.

In assessing eligibility for a herdnumber it must be remembered that the interests of disease control are paramount and that the determination of the epidemiological unit extends beyond TB control as the same
number is also used for certification and control purposes in the event of an outbreak of a class A disease such as FMD and therefore it must be established that as a minimum;

A. the herd is managed at all times as a separate epidemiological unit without intermixing or close association with bovine animals from other herds,

B. the herd has an identifiable keeper (i.e. one person) primarily responsible for the health and welfare of the animals and compliance with all animal health regulations,

C. adequate handling facilities, not shared with or used by any other herd, are available to carry out satisfactory testing,

D. the herd should, as far as possible, have separate farm equipment, housing and fodder i.e. tractors, trailers, fodder or other equipment should not routinely move between the applicant herd and any other establishment and

E. satisfactory arrangements are in place to prevent disease spread due to waste disposal.

Please note that separation means a complete division of operations such that:

a) there are separate entrances, (to/from each epidemiological unit)
b) entry points onto other adjoining lands, not part of the application, should be permanently blocked,
c) perimeter fencing should be stock-proof at a minimum and should also prevent direct contact with stock on contiguous land,
d) independent and separate facilities exist (i.e. separate crush, separate feeding and watering facilities),
e) adequate facilities exist for the purpose of inspection, isolation, loading, unloading, marshalling, watering, feeding, housing as appropriate and treatment of animals and
f) adequate provision has been made for animal bedding and the collection of manure and wastewater

Additional herd numbers facilitate the control or management of disease outbreaks focussed on one or more places that because of geographic or enterprise separateness do not share the same epidemiological risks. The distance between parcels of land and the duration of time stock spend on such land should also be considered in determining the advisability/necessity/eligibility for additional herdnumber(s). Where blocks of land are adequately separated and used predominantly/exclusively for different enterprises or management functions, e.g. running a milking dairy herd and fattening beef stock a distance apart, and stock use such land exclusively or for periods/ blocks of time (e.g. for summer grazing or winter feeding) then, for disease control reasons, such blocks should be regarded as requiring separate herdnumbers and movement notification to AIM. Multiple herdnumbers of this nature should be associated on AHCS and by virtue of having one or more herdowners in common will also be linked in CCS.

Where a herdnumber is already in existence, but where the conditions/criteria required to qualify for a herdnumber are no longer being adhered to (e.g. where inter-mixing of animals occurs or where stock are overwintered in the same shed or in the same yard but movement notification has not been made to AIM) then, in addition to cross reporting the breach of terms and conditions for eligibility for a herdnumber, consideration must also be given to prosecution under both TB and Bovine Identification and Movement Regulations. If the persons involved are DAFM staff members (including spouses/partners of DAFM staff members) their supervisory officers and personnel division should be informed immediately. In addition, the number/those numbers should be assessed with a view to amalgamation or withdrawal immediately to reflect the principle that for disease control one epidemiological unit is eligible for only one herdnumber. All animals under common management should be amalgamated under a single herdnumber (preferably a new number unless all parties are in agreement as to which number they wish to retain) and the animals recorded in that number on AIM. The various persons with an interest in the herd should be registered as herdowners, of the single epidemiological unit, and they must nominate a single keeper in whose name the herdnumber should be registered. The necessary changes should also be made to AHCS records. The assignment or withdrawal of herdnumbers should not be delayed pending the nomination of a keeper.

Under Regulation 3(7) of SI 58/2015 the Minister “may nominate a natural person to act as keeper of that bovine and the person so nominated shall fulfil the function of a keeper”.

3. Test procedures

3.1 Test instructions

Instructions for performing the single intradermal comparative tuberculin test (SICTT), in accordance with the EU Directive, (Appendix 1) and OIE requirements and the Irish bTB eradication programme are contained in the annual ERAD document ER4 “Conditions and instructions for Veterinary Practitioners
involved in testing and sampling under the bovine tuberculosis eradication programme” (See Appendix 2) which is reviewed annually and revised as necessary before sending a copy to each veterinary practitioner engaged in tuberculin testing at the start of each year as part of the annual contract renewal requirements.

In order to maintain official approval to conduct tuberculin testing each veterinary practitioner is required to acknowledge receipt of the ER4 document and confirm that the contents have been read, understood and will be adhered to at all times. He/she is also required to declare acceptance of these instructions and willingness to carry out testing/sampling in accordance therewith. In summary this document details the individual test approval, advanced itinerary, equipment required, the animal identification notation, the injection site preparation, the injection technique, the measurement of skin thickness on both days, the method involved in reading the results of the tuberculin test and the requirement to identify reactors for segregation, assembly and security purposes. The ER4 has legal standing under Regulation 7(2) of SI 58/2015 (See Appendix 1c). A TB Test training DVD which demonstrates the correct application and interpretation of the tuberculin test in accordance with national and international legislation has been produced by DAFM and circulated to all PVPs, VIs and WTVIs. Copies are available from ERAD HQ and Regional Offices.

Compliance in relation to the submission of an advanced itinerary (ER9) for each and every test for individual test approval is a legal requirement. Tests carried out on times and dates other than as submitted in accordance with ER4 instructions are therefore unapproved and accordingly illegal. Such tests may be declared invalid by the RVO and rejected for upload by the submitting PVP. PVPs who fail to comply with ER9 requirements should be interviewed by the RVO/AMT and put on notice that failure to comply will result in loss of approval to test.

3.2 Quality Control of testing

The compliance and performance of each veterinary practitioner in the operation of the eradication programme are monitored regularly using key performance indicators from AHCS records (ER13A). These data enable analysis and comparison of testing performance between peers and over time. Those whose performance are found to be out of line with their peers, as well as a random sample, are selected for targeted supervision, while actually performing a test, or other follow up as deemed appropriate by DAFM. There is no category of PVP or test type exempted from inspection while performing any test or by way of animal and other checks following a test. Additional PVPs may be therefore selected for supervision by RVOs on foot of information coming to light during any checks or investigations including the outcome of QC IFN-γ assay and inspection of animals nominated as reactor (See Section 8). Standard operating procedures for Veterinary Inspectors when carrying out supervisions of Veterinary Practitioners are included in Appendix 2a. Selected PVPs should be the subject of unannounced routine supervision, while physically conducting a TB test (ER13 – supervision report - See appendix 2b). Instructions in relation to supervisions are detailed in ERAD circulars which may be subject to change due to policy enhancements. These instructions relate to the number and type of supervisions to be carried out and the data to be recorded on specific forms during such supervision e.g. ER13, ER13B and ER13C. It is the responsibility of the VI to monitor the quality of testing by PVPs who carry out testing in his/her area, including utilising information on ER13A, findings at ER76B investigations (Section 7) and traceback and trace onward notifications (Section 12) and to apply follow up action in accordance with current policy instructions. Accordingly under special circumstances non-routine inspections may also have to be conducted.

3.3 Veterinary Certification

DAFM, recognised as the Competent Authority by the EU, is obliged under EU legislation to ensure that tests are performed correctly. For instance, Article 3 of Directive 64/432/EEC requires that “Each Member State shall ensure that only animals that fulfil the relevant conditions laid down in this Directive are sent from its territory to that of another Member State” and Article 15 requires that “Member States shall take the appropriate specific measures to penalize any infringement of this Directive whether by a natural or a legal person.”

In addition, Article 5 of Council Directive 96/93/EC on the certification of animals and animal products states (1) Member States shall introduce such checks and have such control measures taken as are necessary to prevent the issuing of false or misleading certification and the fraudulent production or use of certificates purported to be issued for the purposes of veterinary legislation (2) Without prejudice to any legal proceedings or penalties, the competent authorities shall carry out investigations or checks and take appropriate measures to penalize any instances of false or misleading certification which are brought to their attention. Such measures may include the temporary suspension of the certifying officers from their duties until the investigation is over. In particular, if it is found in the course of the checks that: “a certifying officer has knowingly issued a fraudulent certificate, the competent authority shall take all necessary steps to ensure, as far as is possible, that the person concerned cannot repeat the offence”. S.I.
RVOs should be guided by the current ER4 as to requirements necessary to ensure compliance with these obligations and the appropriate follow up responses to non-compliances. It is the responsibility of the area VI under the aegis of the RVO SVI and AMT to ensure that testing quality and Veterinary Certification in his/her area meets the required standards.

**Recovery of costs for additional controls necessitated by non compliance**

The Department’s policy under EU and national legislation requires that veterinary practitioners be charged for any additional controls such as inspections, testing, blood sampling or other investigations over and above normal control activities resulting from detection of non-compliance (Appendix 2 and 2c)

### 3.4 Practice inspections

Veterinary practice inspections are conducted by veterinary inspectors for a variety of purposes during the course of their duties on behalf of DAFM including, but not limited to, cases where compliance with the administration requirements of the bTB eradication programme are not optimal. During the course of any inspection a Veterinary Inspector may examine some or all of the following: the equipment and related computer software to be used in the field, the test organisation administrative procedures, testing/sampling arrangements, individual AGR code use, with particular reference to ensuring the integrity of certification processes, AHCS1 procedures i.e. changes to veterinary certification already provided to AHCS by the PVP, animal profile discrepancies, management of animal passports during test and in particular passports for inconclusive reactors (return to RVO) and reactors disclosed at test, tuberculin storage and stock control procedures, storage of tags for temporary ID purposes, testing equipment maintenance and syringe certification records (See Appendix 2d).

### 4. Test Types (TT)

The Single Intradermal Comparative Tuberculin Test (SICTT) is conducted under the following test types.

| (1) | Round test | (5g) | Forward trace S.C.T. (animal) |
| (2) | New Herd Special Check Test (S.C.T.) | (5h) | Miscellaneous (animal) S.C.T. |
| (3) | Inconclusive reactor re-test | (6) | Private test |
| (4) | Reactor re-test | (7a) | Post depopulation C.T. |
| (5a) | Classification related S.C.T. | (7b) | Post de-restriction C.T. |
| (5b) | Associated to a reactor herd S.C.T. | (8) | Contiguous herd test |
| (5c) | High incidence Area/DED and Miscellaneous C.T. (herd) | (9a) | Factory lesion test |
| (5d) | Factory return (Animal/herd) obsolete | (10a) | Balance of herd test (factory lesion) |
| (5e) | OTF regain status S.C.T. | (10b) | Balance of herd test (private test) |
| (5f) | Backward trace S.C.T. (herd) | (10c) | Balance of herd test (inc retest) |
| | | (10d) | Balance of herd test (fwd trace S.C.T.) |

Other tests: Interferon Gamma Assay, ELISA Test and Anamnestic ELISA (see Section 9)

### 5. Test Type Ranking

**Restricted Herds** (Officially TB Free disease status suspended or withdrawn and/or trading status suspended or withdrawn):

The **trading status** of all herds restricted due to tuberculosis is set at S (Suspended) or W (Withdrawn) on AHCS signifying that such herds cannot trade in cattle on the open market. Trading status is also suspended for TB control and programme management reasons without an actual ongoing TB diagnosis/outbreak.

In herds currently with OTF status withdrawn or suspended due to tuberculosis only Test Types 3, 4, 5D, 9, and 10 apply. Test types 3, 4, 9, and 10 are automatically prompted at follow up by AHCS as they have priority over all other test types.
The first herd test post de-restriction must be a post-depopulation CT Test (7a) or a Post-derestriction CT Test (7b) except in the case of
(a) herds where the suspicion of tuberculosis has been resolved with a negative result under the singleton protocol, or
(b) D or L risk herds without any skin test reactors following a confirmed FLR (TT9 and TT4), which revert to Test Type 1.

See Sections 11 Slaughterhouse Suspect-TB/Factory lesion policy, 13 ‘Singleton’ Protocol, 15 Atypical herds and circular ER7/2016 which lay down procedures to resolve these herds in accordance with the Directive.

Test Type Priorities

<table>
<thead>
<tr>
<th>Priority</th>
<th>TT DESCRIPTION</th>
<th>TT No.</th>
<th>Trading Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>REACTOR RE-TEST</td>
<td>4</td>
<td>Withdrawn/Suspended</td>
</tr>
<tr>
<td>3</td>
<td>FACTORY LESION RETEST</td>
<td>9a</td>
<td>Withdrawn</td>
</tr>
<tr>
<td>4</td>
<td>BALANCE OF HERD TEST (private/misc test)</td>
<td>10b</td>
<td>Withdrawn/Suspended</td>
</tr>
<tr>
<td>5</td>
<td>BALANCE OF HERD TEST (forward trace test)</td>
<td>10d</td>
<td>Withdrawn/Suspended</td>
</tr>
<tr>
<td>6</td>
<td>BALANCE OF HERD TEST (inc retest positive)</td>
<td>10c</td>
<td>Withdrawn/Suspended</td>
</tr>
<tr>
<td>7</td>
<td>BALANCE OF HERD TEST (factory lesion)</td>
<td>10a</td>
<td>Withdrawn</td>
</tr>
<tr>
<td>8</td>
<td>POST DE-RESTRICTION C.T.</td>
<td>7b</td>
<td>Free H or L</td>
</tr>
<tr>
<td>9</td>
<td>POST DEPOPULATION C.T.</td>
<td>7a</td>
<td>Free H herd</td>
</tr>
<tr>
<td>10</td>
<td>CONTIGUOUS HERD TEST</td>
<td>8</td>
<td>Free/Suspended</td>
</tr>
<tr>
<td>11</td>
<td>ASSOCIATED TO A REACTOR HERD S.C.T.</td>
<td>5b</td>
<td>Suspended</td>
</tr>
<tr>
<td>12</td>
<td>CLASSIFICATION RELATED S.C.T.</td>
<td>5a</td>
<td>Free</td>
</tr>
<tr>
<td>13</td>
<td>BACKWARD TRACE S.C.T. (herd)</td>
<td>5f</td>
<td>Suspended</td>
</tr>
<tr>
<td>14</td>
<td>OTF REGAIN STATUS S.C.T.</td>
<td>5e</td>
<td>Suspended</td>
</tr>
<tr>
<td>15</td>
<td>HIGH INCIDENCE AREA /DED/MISC C.T.</td>
<td>5c</td>
<td>Free</td>
</tr>
<tr>
<td>16</td>
<td>INCONCLUSIVE REACTOR RE-TEST</td>
<td>3</td>
<td>Suspended +/- Derogated</td>
</tr>
<tr>
<td>17</td>
<td>FORWARD TRACE S.C.T. (animal)</td>
<td>5g</td>
<td>Suspended</td>
</tr>
<tr>
<td>18</td>
<td>FACTORY slaughter out of date S.C.T. (herd) obsolete</td>
<td>5d</td>
<td>Suspended</td>
</tr>
<tr>
<td>19</td>
<td>MISCELLANEOUS ANIMAL TEST</td>
<td>5h</td>
<td>Free/Suspended</td>
</tr>
<tr>
<td>20</td>
<td>ROUND TEST</td>
<td>1</td>
<td>Free</td>
</tr>
<tr>
<td>21</td>
<td>NEW HERD S.C.T</td>
<td>2</td>
<td>Suspended</td>
</tr>
<tr>
<td>22</td>
<td>PRIVATE (Movement) TEST</td>
<td>6</td>
<td>Free</td>
</tr>
</tbody>
</table>

Clear Herds:
Where a ‘clear’ herd is scheduled for a test, which has not yet commenced, and a test of higher priority is required at an earlier date than the test scheduled, the prioritising of test types for the new listing should follow the rules below:-
Test type 7 has priority over 8, 5 and 1.

Similarly test type 8 has priority over types 5 and 1 and finally
test types 5 have priority over types 1, 2 and 3.

Where appropriate such as when a herd is being put on a contiguous programme and the next test due is a TT7 then a TT7 should be re-scheduled to an earlier defined date determined by the VI based on contiguous programme rules, rather than left to the farmer’s choice of date, 3-8 months, from the clearance test, and the herd maintained on the contiguous test programme on AHCS to ensure that the sequencing of subsequent contiguous tests proceeds as laid out in Section 9.
Where trading status has been suspended for administrative and programme reasons and set to Status S (Suspended) on AHCS, e.g. failure to conduct a test within a given timeframe, breach of an official notice or Regulation of SI 58/2015, or where out of test animals have been sent for slaughter, or a contiguous test or 1st test post de-restriction is due and the allowed trading time since the last herd test has elapsed (4-months and 3 months respectively) then the listing will require test types other than 4 and 9.

The Activity status on AHCS may also used to suspend a herd status for other reasons.

### 6. Herd Classification System

Herd classification is applied to ensure that a herd is managed in a manner commensurate with the TB status and risk appropriate to the herd. At each test, suspect lesion notification, trace-back or trace-forward notification the Veterinary Inspector will on epidemiological grounds, utilising all information available on AHCS (herd and animal history, traceback, contiguous and associated herd status), Herdfinder and local knowledge as appropriate to the particular case determine the most appropriate action and follow-up, including as necessary updating any of the parameters of the herd classification system.

The classification system categorises herds based on the following three parameters:

#### 6.1: Trading Status

<table>
<thead>
<tr>
<th>TB Status Group / Code</th>
<th>Code</th>
<th>Meaning</th>
<th>Reasons</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trading Status</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>F</td>
<td>F</td>
<td>Trading Status Free</td>
<td>Normal OTF herd Inconclusive R herd derogated for internal trade</td>
</tr>
<tr>
<td>S</td>
<td>S</td>
<td>Trading Status Suspended</td>
<td>Animal not from OTF herd; Test not completed; Positive test; PM TB suspect; Unresolved status; Failure to test; Singleton; Trace; animal out of test slaughtered; Epidemiological enquiry; H-herd &gt;3-months post-derestriction awaiting TT7; contiguous herd due test and &gt;4-months since last clear test.</td>
</tr>
<tr>
<td>W</td>
<td>W</td>
<td>Trading Status Withdrawn</td>
<td>OTF status withdrawn; Positive reactor (defined below); Clinical TB (confirmed); Animal not from OTF herd; Test not carried out; Trace; Failure to test or C &amp; D required.</td>
</tr>
</tbody>
</table>
6.2: TB risk status of herd

<table>
<thead>
<tr>
<th>TB Risk</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>D</td>
<td>Default</td>
</tr>
<tr>
<td>H</td>
<td>At Risk Higher</td>
</tr>
<tr>
<td>L</td>
<td>At Risk Lower</td>
</tr>
</tbody>
</table>

6.3: Disease Status of the herd

<table>
<thead>
<tr>
<th>TB Disease Status</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Clear</td>
</tr>
<tr>
<td>1</td>
<td>Restricted</td>
</tr>
<tr>
<td></td>
<td>Disease Status with Reactors in Last Test</td>
</tr>
<tr>
<td>2</td>
<td>One clear test completed.</td>
</tr>
<tr>
<td>3</td>
<td>Scheduled for Inconclusive reactor retest</td>
</tr>
</tbody>
</table>

Range: Clear (0) to Restricted 1; 2 (1 Reactors on last test; 2 One ‘clear’ test completed) Inconclusive reactor 3.

A herd restricted under Irish legislation is, for the purpose of the TB eradication programme, equivalent to OTF status withdrawn or status suspended in Directive 64/432/EEC. Irish legislation authorises the restriction of a herd and does not dictate the duration of the restriction period. However, to ensure that trading certification is not compromised in any way V.I.s are mindful of the requirements of the trade Directive (64/432/EEC) when derestricting herds and AHCS has been programmed to prompt compliance with this Directive. Compliance with the Directive and with the programme as approved by the EU is essential. The Directive requires that Status be withdrawn when the presence of tuberculosis is confirmed by the isolation of M. bovis (regardless of jurisdiction in which the tuberculosis was confirmed).

Status may also be withdrawn, under the Directive, if:
- a. the conditions to retain OTF status are no longer fulfilled, or
- b. classical lesions of tuberculosis are seen at post-mortem examination, or
- c. an epidemiological enquiry establishes the likelihood of infection, or
- d. for any other reasons considered necessary for the purpose of controlling bovine tuberculosis.

Where status is withdrawn tracing and checking of any herd considered as epidemiologically related must be undertaken. The status must remain withdrawn until cleansing and disinfection have been completed and all eligible animals have had two consecutive clear tests, the first conducted a minimum of 60 days and the second a minimum of 4 months and a maximum of 12 months after the removal of the last positive reactor.

For Directive purpose, then a ‘positive reactor’ results in herd status OTF-withdrawn and is an animal
- in which the presence of tuberculosis is confirmed by the isolation of M. bovis on laboratory examination, or
- in which classical lesions of tuberculosis are seen post-mortem, or
- where epidemiological enquiry has established the likelihood of infection, or
- where it is considered necessary for the purpose of controlling bovine tuberculosis to consider the animal ‘positive’ e.g. test reactors, including those in otherwise singleton protocol eligible herds where the SICTT has shown an avian/bovine difference of 12mm or more and/or the avian/bovine ratio on IFN-γ assay indicates the animal is infected. (NB this does not indicate that all singleton reactor animals must be sampled for IFN-γ assay).

In summary, to comply with the Directive, the officially tuberculosis-free status of a herd is to remain withdrawn until cleansing and disinfection of the premises and utensils has been completed and all animals over six weeks of age have reacted negatively to at least two consecutive tuberculin tests, the first no less than 60 days and the second no less than four months and no more than 12 months after the removal of the last positive reactor.
An OTF-suspended herd status is basically an unresolved or as yet undetermined status applied and remaining in place pending a decision as to the true TB infection status of that herd.

**Disease Risk Range -**

The Risk of the herd being positive at the next herd test:

- **H** (Higher)
- **L** (Lower)
- **D** (Default or least risk of a positive test and includes singleton herds)

This classification system results in a matrix comprising nine classes of herds.

<table>
<thead>
<tr>
<th>Risk of a positive next test</th>
<th>Current Status Restricted</th>
<th>Current Status Clear</th>
</tr>
</thead>
<tbody>
<tr>
<td>H</td>
<td>H1</td>
<td>H0</td>
</tr>
<tr>
<td>L</td>
<td>L1</td>
<td>L0</td>
</tr>
<tr>
<td>D</td>
<td>D1 (singleton awaiting tissue test)</td>
<td>D0</td>
</tr>
</tbody>
</table>

Herds are initially classified H or L following a restriction and may be updated from L to H on the basis of the cumulative severity over the entire TB breakdown.

**Risk Classification H:**

Data analysis has repeatedly confirmed\(^6\) that the risk of repeat breakdowns arises when 2 or more TB infected animals are detected and the infection was acquired within the herd. The graph below (Olea-Popelka et al. 2004)\(^7\) demonstrates that the survival time for herds following a breakdown with two reactors is not substantially longer than that for herds with breakdowns involving greater numbers of reactors.

**Overall survival curves (no BTB breakdown) by exposure severity during the 1995 episode**

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Thus herds with two or more TB infected animals over the course of the episode (duration of restriction under TB Regulations), indicating within-herd TB spread, as evidenced by the detection of lesions or by animals failing the SICTT at standard interpretation, or a combination of both, are ordinarily classed H (Infection with concurrent spread → Higher risk of positives at next herd test i.e. a ‘H’ breakdown episode) and higher risk of repeat breakdown in the future. Clegg et al in 2015 re-assessed the attribution of risk of future breakdown and confirmed that the risk increased when 2 reactors were disclosed so that the appropriate cut-off point for ‘H-risk’ classification still remained at 2 reactors and also demonstrated that the risk remained far longer than 2 years post de-restriction. It would appear that the original 1988 Categorisation document which had applied a 5-year classification duration may have been more accurate than current policy.

On epidemiological grounds, utilising all information available on AHCS (herd and animal history, traceback, contiguous and associated herd status), Herdfinder, local knowledge and with the agreement of the SVI, a Veterinary Inspector may where lesioned animals or other reactors have been traced back to a herd, and it is considered probable that these animals acquired TB while in the herd to which they have been traced back, classify a herd as H even though lesions/reactors may not have actually been identified/confirmed in that herd.

A Veterinary Inspector may determine, on epidemiological grounds, with the agreement of the SVI that a herd is unlikely to be infected with M. bovis or that the infected animals are unlikely to have been infected in the herd of disclosure (no within-herd spread) and that therefore H classification is inappropriate e.g. herds, where the infected animals were all “recently” introduced and infected in their herd of origin prior to introduction, thus including the majority of feedlot herds as described in Section 19, or in NSI/Atypical herd situations and such herds should be classified L (below).

**Risk Classification L:**

All breakdown episodes not classified as H are classed L (Lower risk of positives with disease spread - i.e. TB infected - at next herd test and lower risk into the future) except in the case of Singletons which satisfy the criteria and pass laboratory analysis which are classed D since they are classified as not TB (See Section 13 ‘Singleton’ Policy). A herd already classified H from a previous breakdown may experience a breakdown that would otherwise be classified as L (e.g. one reactor or one lesion but no concurrent spread) but such a repeat breakdown will not alter the prior H classification risk of the herd. However, if it occurs late in the existing H clearance cycle (e.g. at final TT5 stage) it may prolong the H classification while the herd undergoes the tests to clear the breakdown (i.e. 2xTT4+1xTT7b). Restricted beef fattening herds, whether or not they meet the criteria to be regarded as feedlots (See Section 19), thereby possibly being exempted from the requirement to have a clear herd test prior to being granted permission to move cattle in, are usually classified as L unless there is or has been TB acquisition/spread within the unit.

Herds classified H1 generally revert to H0 following a minimum of two consecutive clear tests, the first conducted a minimum of 60 days and the second a minimum of 4 months, and a maximum of 12 months, after the removal of the last positive reactor.

H0 herds will rejoin the default class, D0, on completing (and passing) a Type 7b test and two Type 5A tests carried out at 3-8 month and six month intervals (7b;5a;5a six monthly testing cycle i.e. 15-months to 20 months clear from time of de-restriction). Note: this duration is likely to be extended in the future as research indicates that the herd remains at higher risk for longer following a H-risk outbreak.

<table>
<thead>
<tr>
<th>Herd Classification</th>
<th>Testing</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>H1</td>
<td>2 x TT4</td>
<td>4 months</td>
</tr>
<tr>
<td>H0</td>
<td>1 x TT7b</td>
<td>3-8 months</td>
</tr>
<tr>
<td></td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td></td>
<td>2 x TT5a</td>
<td>12 months</td>
</tr>
<tr>
<td>D0</td>
<td>Routine testing</td>
<td></td>
</tr>
</tbody>
</table>

---

H1 \(\rightarrow\) 2 x TT4 (4months - clear) \(\rightarrow\) H0 \(\rightarrow\) 1 x TT7b (3-8 months) + 2 x TT5A (at six month intervals) \(\rightarrow\) D0 i.e. to go from H1 to D0 the herd must complete and pass 5 tests over a 19 - 27 month period.

L1 \(\rightarrow\) 2 x TT4(4months - clear) \(\rightarrow\) L0 \(\rightarrow\) 1 x TT7b (6months) \(\rightarrow\) D0 Herds classified L1 revert to L0 following typically two clear reactor retests carried out at 60 day intervals (N.B. see also Sections 11 and 13). L0 herds will rejoin the default class, D0, on completing a Type 7b test.

Each time reactors, suspect TB lesions at slaughter etc. are disclosed the VI must re-consider the epidemiological information as above utilising all information available on AHCS (herd and animal history, traceback, contiguous and associated herd status), Herdfinder and local knowledge to ensure the herd risk classification is correct and appropriate follow-up and test intervals are optimised.

Depopulated herds will rejoin the default class, D0, on completing one clear Type 7a test. When bought-in reactors occur on a TT7a the herd should ordinarily be classified as L pending resolution of this breakdown, unless it is clear that there is within herd spread occurring (Section 16 Depopulation).

The default class D0, comprising herds with the least risk of having a TB reactor on the next test, would normally be scheduled for a Type 1 test, unless scheduled as part of the Contiguous or Area Special Check Test Programmes. L0 and H0 herds will be scheduled for either TT7A or 7B but TT5A may be replaced and any test advanced if part of a Contiguous or Special programme.

D0, LO or HO herds not tested during a defined period, depending on test type listed, should have their trading status suspended (or withdrawn at the discretion of the SVI depending on the seriousness and nature of the individual case) by virtue of regulations. These herds will then ordinarily retain their original risk status on completing one clear herd test e.g. FH0 \(\rightarrow\) SH0 \(\rightarrow\) FH0.

D3 herds are OTF status suspended for the presence of an inconclusive reactor. Under the Directive such herds may qualify for derogation (if herd/animal has no known TB contact and are adjudged unlikely to be infected) and so allowed to sell stock for home trade only (Section 14 Inconclusive Reactor Policy). If the Inconclusive reactor is to be slaughtered it must be accompanied by a permit stating the animal is an inconclusive reactor which will ensure the slaughter plant is aware of the animal’s status so that EU Regulations with respect to slaughter and post mortem requirements are met. If the subsequent OTF regain status SCT (TT5e) has a further inconclusive reactor this is not a clear test and is not eligible for further derogation until the status of that further inconclusive reactor(s) have been resolved.

7. Epidemiology

All TB breakdown herds from first restriction until clearance are subjected to epidemiological assessment as each test, on live or dead animals, is reported and interpreted utilising the appropriate interpretation level. During the course of this assessment, which encompasses utilising all information available on AHCS (herd and animal history, traceback, contiguous and associated herd status), Herdfinder and local knowledge to evaluate the source and possible spread of infection, the breakdown will be risk assessed and the appropriate risk classification (Section 6) as laid down in the bTB Eradication programme applied. In addition, decisions with respect to the need for prioritising a farm visit, forward/back tracing (Section 12) will be progressed, in consultation with the SVI if necessary, as will creation of a contiguous programme (Section 10) where relevant i.e. generally mandatory for H-breakdowns, ER76B farm visit and/or repeated visits plus decision as to use of IFN-\(\gamma\) (Section 9) on particular cohorts on one or more occasions.

Where herd status is withdrawn (see Section 6) tracing and checking of any herds and animals considered to be epidemiologically related is to be undertaken in accordance with Directive 64/432/EEC Annex A I 3B (See Appendix 1).

While in practice staff shortages and financial considerations may mean it is impossible to visit all TB breakdowns with smaller number of reactors, all herds experiencing a breakdown that would result in an H classification (see Section 6) warrant a full (ER76B) investigation and report. Ultimately it is the SVI who will deploy the RVO available resources as appropriate. An ER76B investigation commences with an office-based examination of all the relevant herd-file and computer records. A farm visit, preferably by appointment, is then undertaken by the VI to collect further information and discuss management aspects,
potential opportunities for spread from the herd and any zoonotic risks with the keeper. Data from this visit should be recorded on an ER76B report form. (See Appendix 3)
Objectives of Epidemiological investigation
The ER 76B refers to a detailed epidemiological investigation by a VI of a disease episode on a holding (i.e. not merely a farm visit) to:
1. Assess reactors, their reactions and the regression pattern (appendix 3a), sample them for IFN-γ QC purposes and assess the degree to which collective results or these checks indicate TB infection (see also Section 9).
2. Ensure reactors are isolated and identify all areas where cleansing and disinfection is required.
3. Identify possible and probable sources of M. bovis infection in the herd.
4. Check classification of the breakdown (Section 6).
5. Identify possible cohort groups of animals in the herd which are likely to be the focus of infection (removal of additional animals, severe I/R, SIT positive, group removal, confinement –ER84).
6. Advise the keeper on appropriate disease control measures to be taken during and after the breakdown for outbreak management. Also check that milk is being withheld and not supplied for human consumption (only suitable for feeding existing reactors).
7. Advise the keeper on the zoonotic implications for the family, farm workers and others potentially exposed and on the best course for management of the outbreak to minimise the risk of zoonotic exposure.
8. Identify and risk categorise animals for forward tracing (Section 12).
9. Identify herds for inclusion in the contiguous programme (Section 10).
10. Arrange sampling of the relevant cohort group (4 above) for IFN-γ assay with the keeper in accordance with policy (see Section 8 and appendix 3) when TB infection is indicated following 1 above.
11. Check that DAFM requirements re herd register are being adhered to and that tracing is therefore accurate and
12. Provide data for the analysis required for policy formulation.
13. If bovine origin infection is unlikely or ruled out and if badger involvement is suspected, the VI will check for evidence of badger activity relevant to the infected cohort to refer to the wildlife unit.

Where, on epidemiological grounds, infection is suspected in untested calves, such as may happen with home bred young calves in previously free herds, the VI should consider subjecting them to an immediate SICTT.

Additional and more detailed epidemiological investigations must be conducted on herds that experience repeat breakdowns in order to determine if current practices in terms of restricted herds are optimal.

8. Interpretation of SICTT

V.I. interpretation of tests carried out on herds in a breakdown should be based on the level of the severity of the breakdown and epidemiological findings utilising all information available on AHCS (herd and animal history, traceback, contiguous and associated herd status), Herdfinder and local knowledge plus the results of QC IFN-γ. Only a V.I. may make the final decision as to the status of an animal or herd and accordingly, based on additional information available to a V.I., the provisional interpretation suggested by the PVP may be overruled and the animal status be regarded by the V.I. as ‘not determined’, in accordance with Regulation 12 of S.I. 58/2015. Under S.I. No. 58 of 2015 a “reactor” means a bovine which the Minister, by reason of a test or otherwise, has reasonable grounds to suspect is TB infected or is capable of spreading tuberculosis. (See Appendix 1c).

ER 4 instructions (Appendix 2) are that when testing a ‘clear’ herd (i.e. clear status before the test) where 2 or more standard interpretation reactors are found, all standard interpretation inconclusive reactors must be identified and tagged as reactors and recorded on the test report - unless instructed by the RVO to the contrary (e.g. Atypical herd). Where the herd is undergoing a contiguous test, all standard interpretation inconclusive reactor animals must be identified and tagged as reactors as a consequence of the herd proximity to a H-risk TB outbreak, unless specific instructions in respect of the herd and interpretation have been issued by the VI following consultation with the SVI. The ER4 does, however, require PVPs to contact the RVO (SVI/area VI) where there is an unusual number of I/Rs relative to Standard Reactors. In such cases the most appropriate response will normally be to desist marking the I/Rs reactor until an IFN-γ assay has been conducted in order to ascertain the true disease status of the herd/animals.
Note: Regarding the reaction to bovine tuberculin, the presence of diffuse or extensive oedema, necrosis, heat, pain at the injection site or swelling, heat or pain of the related pre-scapular lymph node is always indicative of likely infection with *Mycobacterium bovis*. Animals showing such reactions to bovine tuberculin (i.e. not merely dependent oedema from an oedematous avian reaction affecting the full side of the neck) are, unless test interference or dependent avian response oedema is suspected and supported by IFN-γ assay results, always reactors, irrespective of the measurements recorded.

S.I. 58/2015 provides that a VI may determine that a reaction is not a normal response to tuberculin or that the SICTT performed was not compliant with conditions to be regarded as a valid comparative intradermal test (e.g. no evidence of avian injection or avian injection high onto crest and/or back onto shoulder i.e. at a non-responsive site) in which case the IFN-γ result should be a guide to determine the animal’s TB status and such animals should not be removed as if they were reactors to the SICTT without full investigation (See Circular ER06/2016 and Appendix 4a). Normal Regression pattern of skin fold increases post Tuberculin injection are given in Appendix 4b.

The chart below shows % standard interpretation and % severe interpretation reactors annually over the last 30 years – reasonably steady at 70/30. The dip in standard reactors and corresponding rise in severe reactors in 2008 is due to the trial involving the use of the IFN-γ Assay conducted that year in high risk herds which resulted in the removal of IFN-γ Assay positive animals as reactor that were not reactors to the SICTT. Since the lesion rate in severe reactors that year was still 22% it is highly probable that the removal of these infected animals was a matter of timing rather than being merely additional ‘random’ animals being removed. The lesion rate in severe and standard reactors has also been relatively constant at between 30 and 40% (range 28-43%) for standard reactors and around 20% (range 10-25%) for severe reactors. In 2015 the figures would appear to reflect QC measures leading to improved test (SICTT) plus increased use of IFN-γ (QC and cohort).

![Graph showing % standard and severe reactors from 1988 to 2015](image)

**Standard Interpretation** should normally be used in clear herds and Lower risk herd breakdowns.

Where infection has not been confirmed in animals already removed as reactor (skin and IFN-γ positive) and/or NSI is considered probable e.g. low grade IFN-γ positive readings in skin reactors, and *M. bovis* infection has not been confirmed in the herd or the rate of confirmation is very low over the course of two tests then interpretation must revert to standard and glands should be collected from any subsequent animal removed as reactor in an effort to detect if *M. bovis* is actually present in the herd. **Note:** when a herd is actively infected with *M. bovis*, even with sensitivities of 50% for gross post-mortem at routine slaughter, one should expect lesions in at least one reactor animal from every 5 reactors removed.
Severe interpretation may be used at any stage in higher risk breakdowns following the epidemiological assessment by the interpreting VI.

When scheduling tests which present for individual interpretation, e.g. reactor retests, high risk test types, or where the VI has requested that the test/herd is presented for individual interpretation, AHCS will prompt either Standard or Severe interpretation and the VI should select the level of interpretation appropriate to the disease risk over-ruling the AHCS prompt when appropriate. Where the interpreting VI is unsure as to the appropriate interpretation level he/she should consult with the area VI or with the agreement of the area VI leave the interpretation to that VI.
The focus for the infected/possibly infected herd, is always to limit the exposure of additional animals to infection and potential sources of infection with a view to bringing the outbreak under control in an expeditious manner. Therefore, as part of the epidemiological assessment of all breakdowns, including breakdowns in beef fattening herds, a review should be made of the herd/area test history and origin of positives and other animals within or originating from the infected group to determine likely origin of the infection. Where the infection originates within the breakdown herd consideration should be given to

(i) serving a confinement notice (ER84) so as to contain the infected group(s) pending a clear retest,

(ii) conducting a clinical examination for evidence of a clinical case,

(iii) removal of additional animals on the basis of current or previous test measurements (use animal test history),

(iv) interpreting the test at SIT level,

(v) additional short interval interferon-γ Assay between SICTTs,

(vi) conducting ELISA for anergic animal detection and/or

(vii) responding to other epidemiological considerations (see Sections 8 and 9 following).

Where an infected group of cattle can be targeted, bearing in mind that heavily infected and transmitting animals may be anergic to test, the appropriate action, regardless of individual animal test results, may be the removal of the entire group, ‘identified’, as reactors and ‘in-contacts’. As herd incidence falls attention to detail in this respect becomes increasingly important in order to maintain a downward pressure on infection levels and to protect other herds/animals from exposure to infection.

In higher risk breakdowns where infection is considered to be present the minimum level of interpretation at subsequent reactor retests in should be:

(a) removal, as reactor, of standard inconclusive reactor animals within or originating from an infected group(s) of cattle, and

(b) depending on the extent of the infection, consideration of removal, as reactor, of animals ‘inconclusive reactor’ to the severe interpretation chart or positive at the bovine site (straight bovine) within or originating from the infected group(s)

Animals, which have been identified and marked as standard Inconclusive reactor at interpretation, will on their next test have “I/C” on the interpretation screen under ‘prev inc’ opposite the animal’s tag number. Animals which were deemed standard inconclusive reactor at some test in their past but not at their most recent test will have “I/C*” on the interpretation screen under ‘prev inc’, opposite the animal’s tag number. Animals so marked should, at breakdown tests or reactor retest, have their full test history reviewed by the Area VI, and their immediate removal should be considered if presenting with bovine readings and/or if
present in a new or continued ‘reactor’ grouping. Research has shown that Inconclusive reactor animals are, for their lifetime, at higher risk of being detected TB infected than cohort clear animals.

Where disclosure of standard interpretation reactors and/or lesioned animals continues into the 3rd reactor retest, the herd test history, ER76B report, post-mortem findings, results of supplementary tests and any other relevant data should be discussed between area VI, SVI and the RSSVI to identify the most appropriate course of action for the herd. The SVI/SSVI at HQ may also be consulted at this point. If the same PVP has been conducting consecutive tests the testing quality should also be assessed and one or more (consecutive) tests conducted by a VI or WTVI. In addition further sampling for interferon-γ Assay should be conducted in groups still producing animals with confirmed infection (See Section 9).

Where a repeat breakdown occurs at the post-de-restriction test (7b), or Classification related Check Test (5A) a full assessment of the herd should be conducted concentrating on the source of the residual or resurgent infection.

Deviation from policy as set out in the manual and reasons for doing so should be recorded on AHCS.

9. Supplementary Testing (Blood testing)

To enable detection of the maximum number of infected and diseased animals in a herd or in a region, Commission Regulation 1226/2002, fully updating annex B of Directive 64/432/EEC, provides for the use of the interferon-γ Assay (IFN-γ) as an adjunct to the tuberculin test. It is also approved by the OIE. The TB-sub-group of the Task Force (DG SANCO) has, furthermore, recommended extended use of the assay in infected herds.

The IFN-γ assay and the SICTT both measure the cell-mediated T-cell response. The IFN-γ assay received national statutory status in 2005 which status was carried forward into SI 58/2015- Regulation 6 – (See Appendix 1c) - thereby facilitating mandatory sampling and the mandatory removal of animals positive to the IFN-γ assay. Failure to co-operate with IFN-γ sampling is regarded as a refusal to comply with legal requirements or to co-operate with the purpose of the bTB eradication programme and thus besides rendering the herdowner liable for prosecution will also jeopardise eligibility for income supplement, compensation etc. and result in a Cross-Compliance notification which may result in loss of Single Farm Payment or other support payments.


The following, prepared by Professor Simon More\textsuperscript{11}, provides a practical primer to understanding the strengths and weaknesses of the IFN-\(\gamma\) assay in an Irish context. In particular giving examples of instances where the IFN-\(\gamma\) assay is most useful to clear herds of infection.

\textit{Three different herds are chosen as examples.}

\textbf{A. A non-infected herd}

Let’s imagine that we first use the IFN-\(\gamma\) assay in a herd of 100 animals that are definitely free of \textit{M. bovis} infection. As suggested by the study in the TB-free Greenfield herds\textsuperscript{12}, we assume a test sensitivity (Se) of 88% and a test specificity (Sp) of 95%:

<table>
<thead>
<tr>
<th>Result of the IFN-(\gamma) assay</th>
<th>Actual disease status</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Infected (D+)</td>
<td>Not infected (D-)</td>
</tr>
<tr>
<td>Positive (T+)</td>
<td>0 (a)</td>
<td>5 (c)</td>
</tr>
<tr>
<td>Negative (T-)</td>
<td>0 (b)</td>
<td>95 (d)</td>
</tr>
<tr>
<td>Total</td>
<td>0 (a+b)</td>
<td>100 (c+d)</td>
</tr>
</tbody>
</table>

Please note that:

- There are no infected animals
- Of the 100 non-infected animals, 95 will test –ve and 5 will test +. This is because the Sp is 95%

Our focus to this point has been on:

- the test Se (the percentage of infected animals that test positive, this being \(a/(a+b)\)) and
- the test Sp (the percentage of the non-infected animals that test negative, this being \(d/(c+d)\)).

Another measure of importance when interpreting diagnostic tests is the positive predictive value (PPV; the percentage of test positive animals that are truly infected, this being \(a/(a+c)\) in the table above). The positive predictive value is extremely useful in the field, as it considers the problem from the perspective of the tester: ‘What’s the probability, given a test positive result, that an animal is truly infected?’ In this non-infected herd, the PPV is \(0/5=0\%\). That is, there is no probability, given a test positive result, that an animal is truly infected. This makes sense, of course. In a non-infected herd, all IFN-\(\gamma\) positives will be false positives.

\textbf{B. An infected herd with a within-herd prevalence of 5%}

Again, we consider a herd of 100 animals, but with 5 animals infected:

<table>
<thead>
<tr>
<th>Result of the IFN-(\gamma) assay</th>
<th>Actual disease status</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Infected (D+)</td>
<td>Not infected (D-)</td>
</tr>
<tr>
<td>Positive (T+)</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Negative (T-)</td>
<td>1</td>
<td>90</td>
</tr>
<tr>
<td>Total</td>
<td>5</td>
<td>95</td>
</tr>
</tbody>
</table>

Please note that:

- Of the 5 infected animals, \(\sim4\) will test positive (Se of 88%)
- Of the 95 non-infected animals, \(\sim90\) will test negative (given a test Sp of 95%)

Again, we calculate the PPV, which is now \(4/9=44\%\). This means that there is a probability of \(\sim44\%\), given a test result, that an animal is truly infected.

\textsuperscript{11}Simon More, Professor of Veterinary Epidemiology and Risk Analysis within the UCD School of Veterinary Medicine, University College Dublin. He is also Director of the UCD Centre for Veterinary Epidemiology and Risk Analysis, Ireland’s national resource centre for animal disease control. He works at the science-policy interface, providing scientific advice in support of national policy-makers, both within government (the national Department of Agriculture, Food and the Marine) and industry, the latter primarily through Animal Health Ireland.

C. An infected herd with a within-herd prevalence of 20%

Finally, let’s consider a herd of 100 animals, of which 20 are infected:

<table>
<thead>
<tr>
<th>Result of the IFN-γ assay</th>
<th>Actual disease status</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Infected (D+)</td>
<td>Not infected (D-)</td>
</tr>
<tr>
<td>Positive (T+)</td>
<td>18</td>
<td>4</td>
</tr>
<tr>
<td>Negative (T-)</td>
<td>2</td>
<td>76</td>
</tr>
<tr>
<td>Total</td>
<td>20</td>
<td>80</td>
</tr>
</tbody>
</table>

There are several key points here:

- Of the 20 infected animals, ~18 will test positive (Se of 88%)
- Of the 80 non-infected animals, ~76 will test negative (given a test Sp of 95%)

Again, we calculate the PPV, which is now 18/22=82%. This means that there is a probability of ~82%, given a test result, that an animal is truly infected.

**In summary**

Looking at these three herds, you’ll notice that there is a substantial change in the PPV with changing within-herd prevalence:

- 0% in a non-infected herd,
- 44% in a herd with 5% within-herd prevalence, and
- 82% in a herd with 20% within-herd prevalence.

The key point is that a positive IFN-γ result is of greatest value in situations where infection is likely. When the within-herd prevalence is high, the PPV value of a positive IFN-γ result is also high. For this reason, the IFN-γ assay should be used solely in high-risk cohorts, that is, in groups of animals where infection is likely. In these situations, a positive result is more likely to suggest infection, and should to be taken very seriously.

This graph, prepared by Eamonn Gormley,\(^1\) demonstrates the % probability in an infected herd that a positive IFN-γ animal is TB infected, and an IFN-γ negative animal is free of infection when the IFN-γ test is

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\(^1\) Associate Professor, and Director of the TB Diagnostics and Immunology Research Centre UCD, with international experience (U.K., France, New Zealand and Ireland). Research includes the immune responses of cattle vaccinated with BCG, anti TB vaccine for badgers and also IFN-γ testing on the Irish national herd. He is involved in several national and international studies on TB in cattle, wildlife and humans and has active collaborations with groups in the US, South Africa, EU and New Zealand. In recent years he has become involved in studies using -omic technologies to investigate bovine host responses to infection with *M. bovis*. One of the key objectives of this work is to identify genetic signatures of disease resistance and/or biomarkers for improved diagnostic tests.
interpreted in parallel with the SICTT, given a particular TB prevalence level in a herd. For example, (blue line) if you get an IFN-γ positive test result in a herd with 30% prevalence (0.3), you can be 80% sure that it is an infected animal. At 5% (0.05) prevalence you are still 30% sure. **Note**: if you want to maximise test sensitivity so as to remove all infected animals, being 30% sure is quite high, and you would not want to take the chance to leave it behind.

If you get a negative IFN-γ test result in an infected herd (red line) it is likely to be a true negative. Thus, even with **50% prevalence**, you can still be > 80% sure that a IFN-γ is a true negative and disease free. When disease prevalence drops below 30%, you can be >90% sure that true negatives are not infected.

In summary, all the data we have and the analysis we have performed in Irish circumstances has highlighted that IFN-γ positive animals in infected herds have a high probability of being truly infected and IFN-γ negative animals even in infected herds have a high probability of being truly non-infected.

If, however, when conducting QC sampling on animals reported as SICTT positive and a cluster with multiple IFN-γ negative animals is disclosed, this is unexpected (see below) and warrants re-sampling using 8hr assay to determine if the reported SICTT result is an accurate reflection of the disease status of the individual animals.

### 9.1 When to use the Interferon-γ assay

The IFN-γ uses heparinised blood samples taken in vacutainers (green top). However, because the test is used on live blood cells initial processing of the IFN-γ samples is required within 8 hours of collection in order to obtain maximum test sensitivity. Blood samples must therefore, be delivered promptly to the laboratory. Please see Appendix 4c for the Protocol for the submission of blood samples for the IFN-γ assay and the strategy for use in various situations. Prior approval for use of ancillary blood testing for bovine TB must be obtained from HQ and should be made on the approved standard form.

The IFN-γ assay and the SICTT both measure the cell-mediated T-cell response and thus in bTB infected animals a considerable overlap (80-90%) between the animals that respond to these tests is to be expected. At the interpretation level optimised for use in Ireland, the assay has a sensitivity of 88% that is comparable to the observed sensitivity of the SICTT (80-90%). IFN-γ assay is used for two purposes in Ireland i.e. for diagnostics at 8hrs and for quality control at 24 hrs. The assay is used for diagnostic purposes at its optimal Sensitivity test interval of <8-hrs to increase Sensitivity of extraction of TB infected cattle where, there are sub-populations of M. bovis-infected cattle that give a positive reaction to the IFN-γ assay and not to the tuberculin test, and vice versa. It should be borne in mind that response to the skin test is suppressed in the peri-parturient period i.e. in the weeks both immediately before and after calving, but the IFN-γ is less affected. Therefore there is enhanced rationale for using the IFN-γ assay prior to calving and early in lactation. Used in parallel, i.e. at the same time as the tuberculin test, the results of the combined tests give a sensitivity of over 90%. The specificity of the IFN-γ assay (90-95%) – 95% in the Greenfield study herds which were TB-free for 5-years prior and during the study period is lower than that of the SICTT (> 99.95%). This precludes the use of this assay as an alternative to the SICTT for screening purposes because of the likelihood of disclosing false positive reactors in genuinely TB-free herds.

For diagnostic purposes the application of the IFN-γ is therefore confined to test situations, in TB infected herds with multiple infected animals, where there is a high probability that undetected M. bovis infected cattle remain in the herd. In such situations it is used in order to identify animals which pose a potential risk of development of latency resulting in future breakdown, either within the current herd or if subsequently moved to another herd. This is the case in heavily infected herds where a regime of combined tuberculin test and IFN-γ assay can be used effectively to remove additional infected animals and thereby shorten the length of time taken to clear the herd and reduce the possibility future breakdown due to residual infection. Currently (at time of writing) the policy is that, **unless** the readings on the QC IFN-γ assay (see next section) for the reactors reported at the SICTT indicate that M. bovis infection is unlikely

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e.g. negative results or low bovine bias even if result is positive, sampling for IFN-γ assay should be promptly undertaken in herds with TB-outbreaks in or from which 4 or more positive animals have already been disclosed. This sampling refers to non-reactor animals for ‘same-day’ assay i.e. whole groups of cohorts to reactors/infected animals or balance of herd as determined relevant and at risk of exposure by the investigating VI and focussing dominantly on breeding animals or other animals that will not be slaughtered in the short-term. It is preferable that samples are taken 10 or more days post tuberculin injection i.e. normally the week following the QC 24-hr gamma on reactors.

The obvious primary target herds for IFN-γ assay therefore are those experiencing a Higher risk status (H) breakdown (see Section 6). These herds are normally subject to an epidemiological investigation, which for the majority, from which 4 or more positive animals have already been disclosed, will also include a field visit, by the attendant V.I. who may be able to refine the targeted animals to particular groups or those associated with particular land fragments with regard to grazing/housing with the reactor animals during the relevant period prior to detection/removal. Where it is not possible to categorise particular epidemiological groups e.g. in smaller herds, all animals aged over 1 year should be tested. Very young ruminants have a high proportion of IFN-γ secreting innate cells (compared with older animals), hence the IFN assay does not work well in very young animals. Accordingly VIs should avoid sampling such animals for IFN-γ assay. Where infection is suspected in untested calves the VI should consider subjecting them to an immediate SICTT.

Sampling at 10 days immediately following initial SICTT reactor disclosure (current policy indicates ≥ 4 positive cases), such that the maximum possible number of infected animals may be removed at the time of the breakdown, is preferable so as to ensure

(a) the maximum number of infected animals are rapidly disclosed,
(b) reduction in
   i. the total duration of the TB-outbreak,
   ii. the number of reactor retests,
   iii. the risk of development of latency causing repeat breakdown, and
   iv. the risk of onward movement of TB infected animals post-derestriction

Note: While still under trial in Ireland, and prior to legal recognition as an official test in 2005, two distinct studies using Irish data showed that in TB infected herds IFN-γ positive SICTT negative animals are 9 times more likely to be disclosed as reactor (during succeeding two tests) or FLR for 18-months. In addition a study from Northern Ireland found that the increased risk for IFN-γ positive SICTT negative animals remained for 5-years.

In herds with larger breakdowns sampling may be repeated one or more weeks after previous reactors have been removed so as to maximise the possibility of achieving the objectives in (a) and (b) above, and truncating the outbreak so as to maximise the possibility of having a clear SICTT at the next r/r which ideally should be carried out by the WTVI or VI. It is accepted that there are circumstances in some herds with extensive breakdowns when the most practical time to repeat a subsequent IFN-γ assay on herds may be in conjunction with an advanced reactor re-test, which should generally be carried out by the WTVI/VI. When following up test interpretation on AHCS VIs should ensure that subsequent reactor retests, particularly 14 reactor retests following higher numbers of reactors which are unlikely to be clear are not delayed due to disclosure and removal of additional positive animals disclosed on IFN-γ assay and reactor retests should be carried out 42-60 days after the breakdown SICTT.

Note: When the presence of further infected animals is suspected the reactor retest may be advanced and commenced 42-days after the previous injection of tuberculin rather than delaying to the date prompted by AHCS which will be 60-days from the last reactor or factory lesion slaughter whichever occurred later.

The assay is particularly useful and should always be used in herds that are considered for depopulation. Given the Irish research demonstrating the significantly higher risk of IFN-γ positive animals subsequently being detected with TB as compared with cohort IFN-γ negatives it follows that when the assay has been used in these circumstances positive animals should be removed as reactors.

The IFN-γ assay is an officially recognised test and the definition of a reactor in Irish law (see above) allows the compulsory removal of IFN-γ positive animals. Analysis of the 2015 outcome of IFN-γ testing revealed that IFN-γ positive SICTT negative animals had a higher proportion positive at post-mortem (20.6%) than animals that were reported as SICTT standard reactors with a IFN-γ negative result (11.8%). This finding was unexpected given the acceptance generally that the IFN-γ will be normally positive ahead of the SICTT thus less likely to show lesions or otherwise be confirmed with TB at post-mortem and the generally held belief that the IFN-γ is more prone to false positive reactors than the SICTT. Decisions not to sample cohorts immediately, in accordance with official ERAD policy e.g. such as when the bovine bias on all or most of the SICTT reactors is negative or low or not to remove IFN-γ positive animals must be approved by ERAD HQ and reasons recorded on AHCS.

Chronically infected herds, risk classification H, are those that have maintained an H status continuously for at least 3-years and/or have experienced repeat breakdowns over this timeframe. Such herds are at continued high risk of repeated breakdown. H herds which experience a further H breakdown within 2 years of previous H-type breakdown should also be targeted for sampling in an effort to remove all infected animals before restoring herd status (appendix 7). All adult animals in these herds should be targeted in an effort to reduce residual infection or possible spread to other herds. These herds should be IFN-γ-assayed at the time of each first Reactor retest by the VI/TAO.

IFN-γ assay may be considered on all Inconclusive reactor animals in non-derogated herds, with the agreement of the SVI, either 10 days immediately post disclosure or at the time of retest provided that samples from such animals can be collected and submitted together with other samples such that there are minimal sampling and submission costs. A VI, with the agreement of the SVI, should also use the IFN-γ assay in herds being considered for derogation where there is any doubt as to eligibility or additional security is desirable (e.g. valuable breeding animals to be sold). A VI must use the IFN-γ assay in herds being considered for derogation where more than one inconclusive reactor animal has been disclosed in the herd. Sampling for such purposes may be conducted by technical staff rather than VIs. As part of the QC process the SVI may use the result, and the actual readings, of the Inconclusive Reactor animals to assess if the animal ought to have been nominated as a reactor by the PVP rather than as Inconclusive Reactor animals.

Assays must be approved by ERAD HQ and arranged in advance with the laboratory to streamline throughput. (Appendix 4c)

For maximum sensitivity samples taken for diagnostic purposes should be submitted to the laboratory within 8 hours and should not be submitted by post unless specifically approved by ERAD HQ.

When IFN-γ assay positives are being interpreted as reactor the RVO needs to ensure that passports are collected so that these reactors may not be inadvertently slaughtered as if these are ‘clean’ cattle.

**IFNγ Assay as a quality control measure**

In its secondary role, in Ireland, IFNγ is used as a QA/QC check on the reported SICTT reactors and is of particular assistance in determining the true tuberculosis status of an animal where

- a) skin measurements are likely to be or are evidently compromised, for whatever reason and/or

- b) where it is suspected that there was ineffective injection of avian tuberculin (i.e. the test is not the SICTT but a positive bovine response is evident) and/or

- c) the herd has a prior or current Atypical reactor profile (significant numbers of reactors, reactor/inconclusive reactor ratio skewed towards a greater number of inconclusive reactors but without normal lesion rate).

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Samples taken for reactor quality control purposes should be posted to UCD for 24hour assay – ordinarily a lower Se (at 24hours) would be expected but is acceptable for QC purposes. (Circulars ER06/16 and ER06/09).

Correlation or Agreement between results (interpretation/outcome) of SICTT and 24hr IFN-γ, should be evaluated utilizing

1) the avian and bovine readings for the SICTT and IFN-γ,
2) the magnitude of bovine bias for both SICTT and IFN-γ,
3) the data recorded on the reactor assessment form during the farm visit in relation to injection site location,
4) the nature and size of reactions,
5) the regression pattern of the reactions viz. a viz. SICTT reading reported at 72-hrs and,
6) the overall results of 24hr IFN-γ assay (GIF R2E – Appendix 3b).

If all or the majority of reactors assayed have a low bovine bias which is generally reflective of the bovine bias on the SICTT then there are grounds to suspect that the cause may not be infection with M. bovis and while the reactors may be taken, consideration should be given to having glands submitted for examination to determine if M. bovis can be confirmed. If M. bovis infection is not confirmed it may then be possible to restore OTF status after one clear test regardless of the number of reactors removed. It would also, most probably, be advisable to assess the optimum time of the year to test such a herd again to avoid a repeat of the occurrence of low grade reactors that presumably were because of exposure to some other organism causing cross reactivity to the SICTT.

While 100% correlation isn’t expected in the case of animals nominated as reactors to the SICTT it is expected that there is normally >80% correlation/agreement between the SICTT and the 24hr IFN-γ assay results. A general lack of correlation between results and/or a negative bovine bias on animals that were reported as exhibiting reactor readings on the SICTT should raise questions about the validity of the SICTT results/readings.

Some of the most common reasons for lack of agreement between the reported SICTT readings/results and the IFN-γ readings/result include that scars, pre-existing lumps, concurrent responses to other products (vaccines, trace elements, anthelmintics and antibiotics) which are injected in the neck in the same timeframe or prior to the SICTT and are mistaken as tuberculin responses. The avian tuberculin injection may have been too high or on the crest of the neck and/or too far back towards the shoulder (or both in combination). Such sites are unresponsive to tuberculin so that coupled with an adequate bovine site the animal may only be positive to the Single Intradermal Test.

The degree of correlation between animals reported as SICTT reactors and 24-hr IFN-γ positive assay has generally raised to over 85% on average since QC-gamma for reactors commenced. This reflects an improvement in the performance of the SICTT generally and a penetration of an understanding that cull animals volunteered as reactor will be rejected causing embarrassment to PVP and farmer alike. Analysis of the 2015 figures showed that the correlation/agreement on the 24-hr QC IFN-γ assay result varies with the magnitude of the SICTT response. Standard SICTT reactors generally had higher agreement (90%+) with the IFN-γ assay than standard inconclusive reactors (~70%) and in the diagnostic IFN-γ assay ~50% of SICTT severe inconclusive reactors were IFN-γ positive. Even in cases where between 4 and 10 SICTT reactors are reported it is expected that there should generally be over 80% correlation with the 24-hr IFN-γ assay results.

Noting the graph above entitled ‘Post Test Probability’ and considering the probability of a negative IFNγ result being likely to be a true negative uninfected animal even in an infected herd the efficacy, efficiency or cost-benefit impact of the bTB Eradication programme is not furthered by the costly removal of non-infected animals as TB-reactors, nor should farmers lose non-infected animals needlessly decimating their herd.

Where poor correlation/agreement between the SICTT and IFN-γ assay results is detected it must be investigated and managed on a case by case basis, as it occurs, examining the 24hr IFN-γ results under the 6 points above to judge the integrity of the reported SICTT result. Consideration must also be given to any

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18 Clegg, Good, Doyle, Duignan, More and Gormley. Relative performance of the tuberculin skin test and Interferon Gamma assay when used in parallel as a diagnostic test in infected herds and as a quality assurance test on Mycobacterium bovis reactor cattle in Ireland – submitted
other material that may have relevance e.g. treatment history (particularly injections to the side of the neck), age of animal, calving history, body condition score, udder confirmation, milk yield, SCC etc. Where the validity of the SICTT result as submitted is in doubt the investigation should, in the first instance include 8-hr gamma sampling of reactor animals. In cases of incorrect SICTT site location follow up should also include PVP supervision whether or not the validity of the SICTT result as submitted is being investigated. Where there is abnormal SICTT injection site regression (See Appendix 3a) the validity of the SICTT should also be considered.

Where there is less than 70% correlation/agreement the VI having considered the totality of the investigation should consult the SVI with a view to carrying out 8-hour IFN-γ assay on all the reported SICTT reactors. As the number of SICTT reactors reported increase it becomes relatively easier to determine an acceptable level of agreement. Where there are more than 10 SICTT reactors and there is less than 70% correlation with the 24-hour IFN-γ assay results all of the SICTT reactors should be subjected to 8-hour IFN-γ assay before a decision is made on whether to remove any, some or all of the reported SICTT reactors. ERAD Veterinary HQ should be consulted in such cases. Where a decision is made not to remove all or some of the reported SICTT reactors and to submit them to further investigation they should be isolated, the herd restricted, passports withheld, milk be withheld from supply (the status of the animals is not determined as per SI58/2015) and the animals subjected to a SICTT by a VI, not the PVP, after 42 days. The animals should not be permitted to be slaughtered in the interim until their actual response to the intradermal injection of tuberculin can be ascertained.

In cases where it has been determined that active TB is not or is no longer suspected such as where there may have been unsatisfactory application of the SICTT, or that the breakdown may be Atypical as a consequence of non-specific infection (see Section 15) it would then be inappropriate to apply or maintain severe interpretation of the SICTT or to conduct the IFN-γ assay on cohorts.

**When to use ELISA test**

In contrast to the IFN-γ assay and the SICTT, ELISA measures the humoral (antibody) response to infection with *M. bovis*. This response normally emerges later and lasts longer than the cell-mediated response (see illustration below). The Anamnestic ELISA relies on the stimulation of the humoral response to tuberculin hence its optimal application at approximately 10 days to a month post tuberculin injection. The ELISA and Anamnestic ELISA tests use serum from clotted blood samples (red top tubes). Despite many years of sampling for ELISA as yet there is no specific Irish data published on the use, Se, Sp, Positive or Negative Predictive Value (PPV/NPV) of current commercially available ELISAs whether used in advance of tuberculin test or anamnestically 10-14 days following the injection of tuberculin. Accordingly it is difficult to make sound recommendations with respect to the use of ELISAs, in Ireland, based on Irish data.

The Anamnestic ELISA test is used when attempting to detect infected cattle that are anergic to the SICTT. For the purpose of this test blood samples are taken (from non-tuberculin test reactors) two weeks after injection for the SICTT. Work done in the CVRL in the 1990s and (same kits no longer available) indicated that the Anamnestic ELISA test had a sensitivity in the region of 60%. However, the specificity of this test may have been up to 95% while the comparative ELISA had a Se of only 30%. The Anamnestic ELISA test measures a serological antibody response that may be useful in situations where the cell-mediated response has failed or has been overloaded.

The application of the Anamnestic ELISA test would thus be confined to known infected herds in which the presence of one or more anergic, clinically normal appearing, animals is suspected, and particularly, in cases in which infection is confined to particular sections of the herd – usually suspected where disclosure of test reactors (standard interpretation IFN-γ assay positive and/or lesioned animals) continues into or past the 3rd reactor retest despite accurate performance and severe interpretation of the SICTT, and despite the use of the IFN-γ assay. Notwithstanding its apparent low PPV its use may be appropriate in an effort to shorten the length of time taken to clear such herds of infected cattle or particularly in herds which might otherwise be considered as candidates for full depopulation and where the use of SICTT in conjunction with the IFN-γ assay has failed to resolve the problem. Approval for ELISA tests should be sought from ERAD.

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Veterinary HQ and tests should be arranged in advance with the laboratory (CVRL). Results should be forwarded to ERAD Veterinary HQ and follow up action taken as appropriate.

The TB ELISA is not a recognised test either in Irish legislation or by the EU and therefore tests are not eligible for EU co-funding. Consequently, animals removed solely on basis of ELISA testing may not be eligible any co-funding, of the bTB eradication programme, from EU Commission unless they confirm as *M. bovis* positive and therefore glands should be collected for laboratory examination.

10. **Contiguous Testing Policy**

Lists of herds contiguous to a TB breakdown herd are compiled dynamically using data from the Departments iMap system compiled from the area nominated by each applicant farmer to IACS when making a claim for SFP. The AHCS system is populated from Herdfinder with a preliminary list from this data. The list should, as far as possible be validated with the index herdowner/keeper prior to the initiation of a contiguous programme.

The preliminary ER 35 gives a herd profile of eligible animals and a phone number where known, of each of the contiguous herds that have submitted a map for the Single Farm Payment (SFP). This information is updated daily from the iMap system. It does not have information on herdnumbers that are not used to apply for Single Farm Payment. Because, under EU rules, the SFP claim relates to all the land farmed by the applicant and is therefore submitted under the applicants ‘primary’ herdnumber this is the number that will appear on the ER35. It is quite probable that the applicant may have various other associated herdnumbers one of which may be the number applicable for the herd actually contiguous if the primary herd number is not e.g. the primary herdnumber for the claim may be a Kerry herdnumber while the actual relevant contiguous land may be in Offaly. Each of the two herds, in Kerry and Offaly respectively, will (should) have its own herdnumber for disease control purposes. Thus if an unexpected herdnumber turns up on the ER35 list it must be checked on AHCS/CCS for associated herds. In any event the herdowner on the ER35 list submitted a claim for payment for the contiguous land and that farmer should know who uses the land. The list is generated at 150m and those herds >25m from the index herd are marked.

The ‘Herd Finder’ software also gives each RVO the capacity to print a map of the index herd and its contiguous herds in colour. This will allow the contiguous herds to be viewed more clearly. The user can determine the ‘buffer’ however the buffers used are ordinarily 25m for TB.

**N.B. If it is the index herd’s number that does not appear to be mapped please check CCS for associated herdnumbers to determine the herdnumber used for SFP claims and review if the total holding claimed (and mapped) under that herdnumber includes the land relevant to the index herd being investigated.**

This preliminary list should then be checked and modified as necessary by RVO staff. Any additions or deletions to the ER35 list of herds contiguous at 25 meters should be recorded on the contiguous herd module of the AHCS. When the ER35 list has been finalised notification of contiguity to a breakdown should be sent to each keeper on the list and herds identified by the VI/TAO as relevant to the breakdown and requiring test then put on an AHCS contiguous programme.

The contiguous testing policy is dependent on the risk classification (H or L) of the index herd. Where herds are contiguous to more than one index herd, they must be put on a programme for each as appropriate. A programme will then automatically switch to the next restricted index herd and continue on AHCS for the contiguous herd until the last breakdown in the last index herd ends.

Contiguous test policy is a fundamental part of the bTB Eradication programme approved for co-funding by the EU therefore, deviation from policy in this respect is not authorised without sanction from the relevant AMT SSVI. In cases where there is deviation from policy there should be a record on the herd file as to the decision of the V.I. so it will stand up to potential future audit.

**Testing policy in relation to herds contiguous to breakdown episodes classed as H (Higher risk) Ref Circular ER 04/2012 (Version 2)**

Herds contiguous to infected fragments of herds experiencing a higher-risk breakdown (H1; H2) should be restricted, pending test, if not tested in the previous four months. Those subsequently determined during the ER76B visit as not associated or relevant to the breakdown e.g. not contiguous to or having had no animals contiguous to fragments associated with the reactor animals should be de-restricted. In any event
the contiguous lands should all be accounted for and the contiguous herds deemed ‘relevant’ to the breakdown should, for the purpose of test listing, be recorded as a contiguous herd on AHCS. A contiguous testing programme should be set up for each herd with a High risk breakdown (see appendix 4). The programme on AHCS lists contiguous tests according to the following rules:

(i) where the contiguous herd was not tested during the period 90 days prior to or subsequent to the breakdown in the index herd, an immediate test listing will issue from AHCS or 
(ii) otherwise the contiguous herd is scheduled at a 120-day interval from the previous test carried out in that period and
(iii) a contiguous test will be prioritised on the basis of the herd’s existing scheduled test (Section 5).

Herds contiguous to a herd experiencing a higher-risk breakdown should remain on a contiguous testing programme with 120-day-roll-over tests schedule while the index herd remains restricted. The end date of the contiguous programme is extended where the index herd discloses further reactors at subsequent reactor tests so that programme is continued; it is automatically pushed out 180 days when the PM is followed up. The programme should not cease until a clear contiguous test (or a test type of higher priority) carried out more than 60 days after the last positive reactor was removed from the index herd. Herds on a contiguous programme to one index herd should be included on all other contiguous programmes if further relevant index herds are identified. AHCS will then automatically maintain the contiguous herd on a testing programme until the next scheduled date for any contiguous test related to that herd passes the end date of the programme for the final relevant index herd.

The V.I. investigating the breakdown in the index herd decides which herds are relevant to the breakdown and therefore decides which herds should go on the programme. He/she may be advised as necessary by the area TAO when the VI has not personally attended the breakdown herd and/or is not fully familiar with the area. If he/she is of the opinion that a herd is not contiguous or not at risk (e.g. animals tested clear after a sufficient duration - >42-days - post housing with no subsequent exposure) then it should be removed from the higher risk contiguous programme. Where an index herd is considered to be no longer infected i.e. is being regarded as an Atypical herd the contiguous programme should be ended.

V.I.s should actively monitor and manage the contiguous programmes in their areas of responsibility and regularly review the herds to be listed for contiguous tests including any that should be added to and removed from a programme.

Standard inconclusive reactor animals should be removed as reactors when identified in herds contiguous to herds whose current episode is classed H. If a VI wishes to deviate from this interpretation a IFN-γ assay must be conducted and the agreement of the SVI sought and recorded on file before the decision is finalised.

When badgers have been implicated in a breakdown if, following survey under the wildlife policy, it is clear that badgers paths extend from the holding of the index herd to one or more other farms outside the 25m contiguity list then such farms should be added to the contiguous testing programme.

Area testing should be co-ordinated where there is an area (de-facto a high-risk area) with a cluster of infected herds. All herds within the area (clear ring of herds or natural disease barrier on the perimeter) should be managed as at risk and testing should organised so that all lands within the area are accounted for and included on the contiguous programme and that no potentially exposed stock omitted from the testing regime.

Testing policy in relation to herds contiguous to herds classed as L (Lower risk) or classed as H but experiencing a lower-risk breakdown episode.

In general there is no requirement to specifically list herds for test if contiguous to a lower risk index herd (L1; 2) or to a herd classified H but experiencing an L breakdown episode. These herds however, require assessment, from an epidemiological perspective, as to the necessity to test contiguous herds. When the SVI undertakes to have contiguous testing in herds contiguous to a herd classified L the SVI should authorise and record, on the index herd file, the reason for the input of these herds as contiguous herd into AHCS and their placement on a L contiguous programme.
11. Factory lesion policy /Slaughterhouse Suspect-TB

Disclosure of granulomatous lesions in non-Reactors at routine slaughter constitutes a suspicion of TB in the herd(s) of origin and must be followed up in compliance with Article 3A(b) of Annex A of the Directive (Appendix 1). Herd status must be immediately suspended pending completion of laboratory examinations.

Suspect-TB lesions found in clean cattle in a slaughter plant at the routine gross ‘fitness for human consumption’ post-mortem examination, which is not to the standard of laboratory necropsy, are reported to the RVO of the supplying herd, on AHCS as Slaughter checks by an automatic email generated following creation of the ER47 at the slaughter plant on the day of slaughter. Slaughter check refers to the examination at the abattoir and a positive result is the finding of a lesion indistinguishable from TB by naked eye which includes a variety of granulomas, neoplasia, parasitism and actinobacillosis among other conditions. See poster 6 section 9. Submission of a suspect-TB lesion (ER47) indicates that a visible lesion has been detected and submitted for laboratory examination. Absence of visible lesion at the laboratory in a submitted sample, that is supposed to have one, should arouse suspicion of substitution of the original sample. If the laboratory is not afforded the opportunity to examine the actual lesion detected in order achieve an alternative diagnosis the gross result in the slaughter plant must therefore be considered as TB confirmed.

Following receipt of the suspect-TB lesion report, the details should be input on a PM test created on AHCS. The OTF and trading status of the herd of origin must then be suspended (restricted) pending laboratory examination known as a Tissue test [a term which refers to the laboratory process to which Slaughter checks (Suspect lesions) are subjected]. Any other relevant herd should be identified and status suspended with the appropriate reason recorded e.g. PM suspect if suspect animal left herd in previous six weeks and Trace if greater than six weeks.

1. Where TB is confirmed the herd disease status of the index herd is withdrawn and the herd may not be derestricted until cleansing and disinfection is completed and two consecutive clear tests conducted, the first (TT9a) at a minimum of 60 days and the second (TT4) at a minimum of 4 months after the removal of the last positive reactor/infected animal.

2. Histopathological examination is carried out on all suspect-TB lesions and is normally accepted as positive/confirmed result. In cases where histopathological examination indicates a granuloma but fails to confirm either TB or make an alternative diagnosis the sample is subjected to culture which may take up to 8 weeks for a negative result (or to PCR with or without culture until reliability of the PCR has been determined).

3. Where TB is not confirmed and an alternative diagnosis is made (i.e. reason for the suspect-TB lesion is stated, such as Neoplasia, R. equi or an actinosp.) or where the laboratory is satisfied to record that the lesion is not tuberculosis (certain factors present or absent) the herd(s) status should be restored (no SICTT required).

4. Where TB is not confirmed, the lesion remains a TB suspect granuloma and no alternative diagnosis is made (i.e. no definitive reason is determined for the suspect-TB lesion) then this is a tissue test with an inconclusive result. The herd status remains suspended as PM suspect pending a clear TT 5E (OTF Regain Status S.C.T.) a minimum of 42 days after the animal left the herd before the herd status may be restored. Both index and trace-back herd, if relevant, should be tested. (Note: failure to confirm TB in this case is not proof of absence of M. bovis).

When the laboratory examinations are completed, details are reported to the factory and the RVO via AHCS. Progress of the laboratory process for suspect samples can be tracked on the lab test queue on AHCS.

In cases where the lesioned animal was physically present in more than one herd:

a) if the Tissue test positive animal left the previous herd during the six weeks prior to slaughter (PM suspect), the herd status should remain suspended/withdrawn until cleansing and disinfection is completed and two consecutive clear tests conducted, the first (TT5f) at a minimum of 42 days and the second (TT5e) at a minimum of 4 months after the removal of the last positive reactor/infected animal;

b) if the Tissue test positive animal left the previous herd more than six weeks prior to slaughter (Trace), the herd status should remain suspended until cleansing and disinfection is completed and one clear herd test (TT5f) is completed;
c) if the Tissue test positive animal was transported directly from the mart (or elsewhere) to the slaughter plant which may have inadvertently recorded the animal as from the herd of the person presenting it and the animal was not actually physically present in this herd, e.g. the presenter can produce a mart receipt for the day of delivery to the slaughter plant, then the RVO should assign the breakdown to the last herd in which the animal was physically present.

N.B.: The V.I. should, in all cases, carry out an epidemiological assessment of the probability of disease being present and apply status, testing and classification accordingly.

Following the disclosure of a suspect-TB factory lesion, if the farmer has not already requested an immediate ‘balance of herd’ test (10a) for the purpose of obtaining permission to move stock inwards, the decision as to the scheduling of the test is left to the discretion of the VI/SVI who will base the decision on an assessment of the risk factors involved [e.g. multiple suspect-TB lesions disclosed, confirmed suspect-TB lesion in an animal not present in a prior TB-breakdown (i.e. less likely to be latently infected), herd history of previous TB breakdown, contiguous herd in a breakdown recently, should be regarded as higher risk] and the likelihood, therefore, that there is an active breakdown in progress in the herd. However, it must be explained to the keeper that, if this immediate test happens to be clear it will not qualify as part of the status restoration procedure if conducted inside the 42 or 60-day timeframe from removal of the infected animal as specified above which is a mandatory requirement under the Directive such that no exemption may be permitted. See Appendix 1. See paper 7 in section 9.

Where one lesion has already been confirmed in an animal that was not recently brought into the herd and lesion(s) is/are disclosed in further animal/s without an obvious alternative source of TB exposure, regardless of the type of herd (dairy/sucker/beef-fattening) an immediate ‘balance of the herd’ (type 10a) test MUST be conducted because this occurrence is highly indicative of an active multiple reactor serious breakdown. Care must also be taken by the VI to be alert to instances of multiple lesion detections in restricted herds as AHCS will automatically push the next test schedule date to a later date as each suspect lesion in the series is detected and it is critical for disease control that a test is done to identify and remove infected animals as quickly as possible. The interpreting VI dealing with a multiple factory lesion/backtrace herd should therefore schedule the next test manually before the date automatically prompted/scheduled by AHCS.

Procedures for processing suspect and confirmed lesions detected in other jurisdictions e.g. Northern Ireland are set out in Appendix 6b and follow up policy in relation to tracing and testing is the same as set out above.

The Lab test and Tissue test queues on AHCS should be managed on a regular basis by the VI on duty so as to ensure timely and appropriate follow up action in each case.

![Graph showing TB submission rates](image)

DAFM monitors the submission rates and confirmation rates of suspect-TB lesions detected at slaughter of non-reactor cattle as a quality control of post mortem surveillance.
12. Tracing Policy

Trace Onward:
Animals that have been identified as at a high-risk of infection with TB and that have moved out of recently restricted herds currently experiencing an ER76 qualifying (Higher risk) breakdown or to which multiple cases have been back-traced should be traced forward to their current location using AHCS and other records and tested. The Directive also requires tracing and testing of all animals that have moved out of a herd which was ‘derogated’ after an inconclusive reactor animal had been detected and which was subsequently confirmed with disease (See Section 14).

The V.I. should refer to the computer generated AHCS Forward Trace Awaiting Notification list of animals that have moved out of the index herd when conducting the epidemiological investigation. These animals should be individually assessed to risk score their probability of failing their next TB test as a consequence of infection acquired in the index herd.

Animals identified as being at higher risk of failing their next TB test, i.e. at significant risk of actually being infected over and above the normal risk of any animal in a reactor herd, and which have not been tested more than 42 days post leaving the herd should be marked as H on AHCS and notified forward to their current herd. These animals should be tested in their new herd to ascertain their disease status.

When an animal is entered onto the higher risk forward trace queue, the V.I. so designating the animal higher risk should be satisfied, on the basis of an epidemiological investigation, that the animal should immediately be listed for a test in the herd in which it is now located as it is probable, given the pattern of the outbreak, that it was infected in the herd from which it moved and is therefore likely to fail its next test. (e.g. (a) if the progeny of a clinically infected dam (otherwise progeny of a reactor is at no additional risk\(^20\)) or if other calves that remained in the herd became reactor so that a source of infection amongst the young calves, such as a TB milk/mastitis, is suspected and thus either all calves or calves that were sold after an identified TB mastitis case calved must be forward traced or (b) if none or very few calves that remained in the herd became reactor so that there is no reason to suspect that calves that left the herd were particularly or any more likely to be infected before leaving than those that remained, then there should be no need to forward trace calves that left the herd).

The VI, in the RVO to which the animal has been traced, in assessing the data provided about the index herd will decide whether to test just the individual animal(s) (see Section 4) or the full herd in which they are now located. The herd to which they moved should be restricted – trading status suspended – because of the high probability, as assessed by the VI of the index herd, of having moved in a TB infected animal. The keeper now in possession of the animal(s) should be informed accordingly.

Animal Health and Welfare Division is notified centrally on AHCS and provided with details of the Health certificate and Traces number of animals assessed as higher risk, which may have been exported, without a test more than 42 days after leaving the index herd, so that the CVO in the importing country can be notified that they have imported an animal designated as highly probable of being infected with TB such that the animal requires attention.

ERAD is notified of animals imported from herds which subsequently experience a TB breakdown. These animals are entered on the TB Imported Animals queue on AHCS which should be routinely checked by the VI on duty and followed up as appropriate.

The VI assessing the data provided about the index herd will decide whether it is appropriate to require the keeper to isolate forward traced animal(s) pending test. Because the purpose is to prevent the spread of tuberculosis the VI may inform the keeper of the risk and direct him to isolate the animal/s in compliance with Regulation 16 of SI 58/2015 and Regulation 28(1) and attach such conditions to a movement permit as considered necessary. Regulation 28(1) is quite broad and the conditions may include a direction NOT to move certain animals to or from a particular location by serving an ER84 notice (See SI 58/2015 Appendix 1c).

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**Trace Back:**

Trace back should be completed in respect of introduced animals that fail the tuberculin test or confirm with tuberculosis on slaughter. The automation of tracing back of newly identified diseased animals is catered for by AHCS. The notification from the index RO will be transmitted electronically via the AHCS network. On receipt of Trace-back notification the V.I. should make a decision as regards listing the herd of origin for test having regard to the current status of the herd, the date of movement of the animal(s) that are the subject of the report and the date of herd tests subsequent to such movement.

In cases where a herd test is being listed and

a) the back traced animal left the previous herd in the six weeks prior to disclosure and no further reactors are disclosed, the herd status should remain **suspended** until cleansing and disinfection is completed and two consecutive clear tests conducted, the first (TT5F) at a minimum of 42 days and the second (TT5E) at a minimum of 4 months after the removal of the last positive reactor/infected animal.

b) the back traced animal left the previous herd more than six weeks prior to disclosure, the herd should remain **suspended** until cleansing and disinfection is completed and one clear herd test (TT5F) is completed.

Where one or more reactors are disclosed on a backtrace test the herd should be treated as any normal herd with test reactors.

**N.B.:** The V.I. should, in all cases, carry out an epidemiological assessment of the probability of disease being present and apply status, testing and classification accordingly.

Back traced reactors and factory lesions detected in other jurisdictions (See Appendix 6) are notified centrally to ERAD and are entered on the Back trace TB Export Positive Queue on AHCS which should be routinely checked by the VI on duty and followed up as set out. The SVI in the relevant RO is notified directly as to the details of the disclosure whether the exported animal was a test reactor or post mortem detection.

**12. Singleton Protocol**

Following disclosure of tuberculin reactors, a herd is classified D1 or re-classified as H1 or L1. Those herds with a single tuberculin reactor and classified as D1 may be considered as candidates for the ‘singleton protocol’ as described in circulars ER/12(12a, 12b)/96. First time single inconclusive reactor animals where the herd owner decides to send the animal for immediate slaughter are not eligible (the animal is not a reactor) (Appendix 7). See also Appendix 9 for paper 3.

Candidate herds are de-facto regarded, epidemiologically, as unlikely to be TB infected and thus must meet the following criteria:

1) **There must be only one reactor disclosed at the index test**

2) **The bovine increase over the avian increase must be less than 12 millimetres (and if a QC IFN-γ is done regard should also be taken for the avian/bovine differential on it also)**

3) **There should be no oedema present at the bovine site.**

4) **The herd must not have had its trading status withdrawn with TB during the 3 years prior to this reactor and**

5) **None of the contiguous herds are concurrently withdrawn status. Herds with single reactors identified on Test type 8, by virtue of the contiguous association to a high-risk TB breakdown, are excluded from eligibility for the singleton programme and should be so excluded by the VI at interpretation.**

6) **Forward traced, high risk animals, or animals that originated in a herd where cohorts were reactor by virtue of their association with and origin in a high risk breakdown herd are ineligible for Singleton Protocol.**

The SVI may, additionally, refuse to enter a herd into the programme, or to allow it continue in the programme on the basis of a consideration of the disease situation in the area as a whole, or the occurrence of subsequent breakdown(s) in previously clear contiguous herds or where infected animals have been traced back to the herd.
The disease status of herds that enter this programme is ‘suspended’ rather than ‘withdrawn’. Thus, under this policy, these herds will be de-restricted where:

- the criteria for eligibility continue to be met and
- TB is not confirmed at post mortem and
- laboratory examination of glands is negative and
- the herd has been subjected to SICTT conducted at least 42 days after the removal of the reactor animal and
- the results of the herd level SICTT are negative.

The (Post-de-restriction Test type 7B) is not applied to Singleton qualifying herds in which tuberculosis is not confirmed. The classification of these herds on de-restriction will immediately revert to FD0. Given the insensitivity of slaughterhouse examinations, laboratory examination and culture failure some herds that are de-restricted under this protocol will actually be TB infected and may subsequently have a confirmed TB breakdown.

**Note:**

- Care must be exercised by the VI when interpreting ‘singleton’ herds on AHCS in cases where further reactors are disclosed at part herd tests or balance of herd tests. In the follow-up screen there are two check boxes opposite singleton the lower of which must be un-ticked in order to record the removal of the herd from the singleton programme. Failure to do so consequently results in the herd remaining as Unresolved on the singleton report.
- In cases where further positive animals are disclosed in the index herd or where a contiguous herd becomes OTW then it must be removed manually from the programme.
- Where TB is regarded as confirmed (lesions, further reactors or epidemiologically) then the herd must be removed manually from the programme and the breakdown must be re-categorised as L or H as appropriate with OTF-status withdrawn.
- In cases where a reactor retest (TT4) has been conducted on a herd with a status D1 prior to entry of a lab test result a warning will appear on screen “Awaiting lab results”. Interpretation of the skin test should be deferred until after entry of lab test result otherwise a second TT4 will be scheduled and the herd will be classified SD2.
14. Inconclusive Reactor Policy

Directive 64/432/EEC as amended requires that where a herd contains an animal(s), which has shown an inconclusive reactor result to the SICTT (in a previously OTF herd) the status of the herd must be suspended (OTF-S) until the animal(s) status is resolved by
(a) passing a further test after a minimum of 42 days or
(b) is negative post mortem and on laboratory examination or
(c) where laboratory examination is not conducted (i.e. the animal is NVL and laboratory analysis has not been carried out) the herd passes a test 42-days after removal of the animal.

PVPs are informed via the ER4 (Appendix 2) that the passport for Inconclusive Reactors must be returned to the RVO – the RVO will then hold the passport until the animal/herd status is resolved. Under Regulation (EC) No 853/2004, which lays down specific hygiene rules for food of animal origin, an Inconclusive Reactor that is sent to slaughter must receive specific post-mortem examination. Thus such animals must be submitted to slaughter ONLY on a permit issued from AHCS, so the plant is alerted to the animal’s Inconclusive Reactor status. It is not permitted under EU legislation to slaughter Inconclusive Reactors at a Local Authority abattoir. Where a farmer seeks a permit to have an inconclusive reactor slaughtered, at that point the animal, and therefore the herd, is regarded as ‘under test’ and thus the herd must be restricted – OTF status suspended i.e. any derogation (see below) previously allowed is rescinded. The herd is still a ‘D’ category and if the epidemiological circumstances have not altered permission to move cattle in (ER37) could be given as long as there is no visible lesion found at slaughter. If a visible lesion is found the herd is then suspected of being TB infected, with a high probability, given that the animal was inconclusive reactor, that it will be confirmed as M.bovis, and consequently it will require a clear test before permission to buy in may issue.

If, at disclosure, the herd is classified D, has not had its OTF status withdrawn in the previous 3 years and there is no epidemiological reason to suspect TB exposure, then a derogation is provided for in the Directive and the VI may thus decide not to issue a restriction notice to suspend the herd’s trading status for local trade (i.e. the VI is making a presumptive determination that the inconclusive reaction is unlikely to be due to TB exposure). In making the decision, to allow or disallow derogation, a VI will consider other factors such as contiguity profile, the bovine profile of the herd of origin of the inconclusive reactor animal(s) where this animal does not originate in the herd of disclosure, or was present as a reactor cohort during a previous TB outbreak, any traceback reactors/lesions in herds of origin or herds contiguous to herd of origin or herd of disclosure. The VI may thus allow animals to leave the ‘derogated’ herd; however, these animals are not eligible for intra-Community trade and where the presence of disease is subsequently confirmed (positive reactor – section 6) any animals that have moved onward since the last clear test must be traced and tested. Under Directive 64/432/EEC Annex A I Article 3A(d). See Appendix 1.

Where there is more than one inconclusive reactor animal the VI may not allow derogation to facilitate the movement of animals from the herd unless all the inconclusive reactors have passed an IFN-γ assay. The VI may also decide to make use of the IFN-γ assay (sample ordinarily will be taken by TAO) as part of the decision process for any particular single inconclusive reactor animal which otherwise meets the herd and animal eligibility criteria for derogation. The IFN-γ assay results and, in particular, the magnitude of the bovine bias, must be discussed with ERAD HQ to determine final disposition for the inconclusive reactor animals. The IFN-γ assay results may also be used to assess if the testing Practitioner should have deemed the animal reactor.

In addition PVPs are informed via the ER4 (Appendix 2) and farmers by letter that animals from a herd with an unresolved inconclusive reactor animal are ineligible for export certification. The deployment of AIM at marts and export locations ensures that no animals from ineligible herds (de-facto OTF-S as per Directive 64/432) are exported. The interpretation and decision chart and the farmer decision tree to resolve Inconclusive reactor(s) is given at Appendix 7.

If the inconclusive reactor animal(s) is not negative at the subsequent re-test (i.e. consecutive tests) this animal is a reactor and must be removed as such. Herd classification is then as per section 6 above and all animals that have left the herd since the time of the last clear herd test must be traced and tested.
There is a high probability that an inconclusive reactor is actually TB infected notwithstanding having passed a retest. **Since 2012 any inconclusive reactor animal that is negative on retest will remain confined to the herd of disclosure for life.** Exceptionally a move may be permitted to a feedlot herd from which the animal must go directly to slaughter (See Circular ER 02 2012). When the Inconclusive Reactor has passed retest the passport, will be returned to the farmer, stamped by the Department, to indicate that the animal may only be moved to slaughter.

When an inconclusive reactor retest (TT3) discloses a reactor, the necessity to carry out a Balance of herd test TT10c should be assessed by the V.I. based on the epidemiological information available.

In herds with a TB breakdown any animals that were previously inconclusive reactor should be considered for removal.

### 15. Atypical Herds

The vast majority of TB reactor herds behave in a typical manner and are progressed uneventfully through their breakdown to clear status. However, within the restricted herd population there is a subset of herds that behave in an atypical manner in that:

1. They produce unusually large numbers of no visible lesion (NVL) reactors (Appendix 8)
2. They have an unusual ratio between standard reactors and standard inconclusive reactors;
3. Reactors that are removed do not usually confirm with TB in the laboratory
4. The bovine bias on the QC IFN-γ assay is generally in the lower ranges even if the animal is positive to the assay, and
5. They experience repeat ‘reactor’ episodes.

These restricted herds pose a challenging management problem. A serious doubt exists as to their true disease status that is not easily resolved. Since 2012, as an enhancement to the programme described below, reactors disclosed in such herds must be specifically targeted for QC IFN-γ prior to removal. In addition, the magnitude of the bovine bias on the IFN-γ assay result will serve as a guide to the actual tuberculous status of the reactor(s). Where there is poor correlation with QC IFN-γ and/or the bovine bias on the bulk of the animals nominated as ‘reactors’ is low the animals should be re-sampled for 8-hr diagnostic IFN-γ assay. Animals clear on IFN-γ or inconclusive reactors showing low bovine bias on IFN-γ in such herds should not be routinely removed as reactor without discussion with HQ.

In 2002 a special programme was commenced for such herds whereby as far as possible they are treated in a standard manner. Interpretation of SICTT is strictly in accordance with Directive 64/432/EEC Annex A I. 3A (b) but given their history a potential NSI problem must be suspect and severe interpretation, as a routine, is not applied so as to avoid unnecessary decimation of the herd. A full epidemiological investigation is required including, where appropriate, laboratory examination, gland culture and environmental mycobacteria check. Where, reactors appear normal but yet TB infection has not been confirmed for some period of time, where magnitude of bovine bias on reactor IFN-γ assay is not indicative of active TB and where all reactors at a first reactor retest are culture negative, that test may be considered clear so that a second reactor retest can be scheduled and the herd derestricted should that test be clear.

The background to this programme and operational instructions together with the original sample letters, are provided in Appendix 8. These herds are tracked by putting them on a ‘special programme’ on AHCS.

Herds that have a history of Atypical breakdowns may also experience genuine normal TB outbreaks. Where such outbreaks occur the QC IFN-γ will show a high bovine bias and such animals must be treated as reactors and the herd be managed as an infected herd pending the resolution of the normal TB outbreak.

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16. Depopulation

Depopulation of an infected herd is a well-recognized method to eradicate disease and is routinely practiced for diseases such as FMD. It also played a significant role in the success of the Irish Brucellosis eradication programme. The intention of the depopulation is that following restocking these farms would be capable of attaining and retaining a bTB free OTF status. However, in the past analysis by CVERA of the subsequent history of herds which had undergone depopulation due to TB showed that, in Ireland, this policy was not effective in removing all sources of infection from the holding and that these herds had the same propensity to experience a repeat breakdown whether or not depopulation was undertaken. The conclusion drawn from the analysis was that depopulation alone was insufficient to ensure that the re-stocked herd would attain or retain an officially free bTB status (OTF) as defined by Directive 64/432/EEC and recommended that the elimination of other on-farm sources of M. bovis was essential to protect the reconstituted herd. A TB depopulation that fails to meet its objective is ultimately of no benefit to the farmer, the neighbourhood or DAFM.

As is normal in the Irish bTB eradication programme, where science and epidemiological research is used to inform policy, the depopulation policy was adapted to take account of these findings and recommendations. The IFN-γ assay and/or the Anamnestic ELISA were required to help ensure that the possibility that the problem within the herd was being driven by an infected bovine is significantly reduced. Herds depopulated are required, as are all TB infected herds, to undertake a programme of cleansing and disinfection as indicated by the investigating officer and the lands are kept free of bovine stock for a period not less than four-months. In addition, as applies for all TB infected herds, a programme of testing of herds contiguous to the depopulated herd is conducted so that these herds are tested when the infection is active in the depopulated herd and also that they are tested at least 60-days after the last infected animal is removed from the depopulated herd. Furthermore, unless it is clear that the breakdown is not related to badgers, a badger removal programme is implemented post-depopulation. The intention to remove other on-farm sources of bTB is therefore fulfilled.

A 2010 evaluation of the impact of herd depopulation on future bTB risk was conducted on herds depopulated for either TB or BSE 2003-2005 inclusive and the outcome for these herds was tracked up until the end of 2009. This study concluded that the depopulation strategy employed in the Irish bTB eradication programme has succeeded in establishing herds that can attain and retain OTF status following restocking and thus the strategy should be maintained as part of the bTB eradication programme. However, this study indicates that when the other on-farm sources of bTB are removed there is no necessity to maintain the H risk classification for such herds post-restocking. In this study infection detected at the TT7a reflected animals that were infected in their herd of origin and therefore classified as introduced with the animal that moved in. As is to be expected with introduced/bought-in infection there is little if any onward spread and the breakdown is transitory with ordinarily two clear tests followed by derestriction. It is therefore recommended that bTB depopulated herds revert to risk classification D post-restocking, with normal SICTT interpretation regimens applicable once the badger population in the vicinity has been reduced by culling (unless they have been eliminated as a probable source of the outbreak) and pending the availability of badger vaccination for TB. If reactors are detected at the TT7a, which should be conducted as soon as possible once restocking is substantially completed (~6-weeks) severe interpretation regimens should not apply as a routine but it should be regarded as an L breakdown and D classification applied post-derestriction.

As regards the criteria used to decide if a herd should be depopulated, it is policy that where the level of infection in the herd is such that, despite standard and repeated tuberculin testing, the application of the Interferon-γ assay, and Anamnestic ELISA (if considered appropriate), epidemiological assessment and strategic removal of individual animals within the herd, disease continues to spread, serious consideration is given to depopulation. In the first instance, the herd or infected group must be subjected to the IFN-γ assay where it has not already been used, and then the suitability for removal of the entire infected group (partial depopulation or in contact removal) must be assessed. When the assay and/or in contact removal has failed to resolve the problem, then depopulation of the herd must be considered. As a more general rule, cases where more than 30% of the herd has tested positive may lead to depopulation being considered, whereas if 50% of the herd are reactors then depopulation must be considered. Depopulation must also be considered

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where the epidemiological assessment determines that control of TB in the herd or area will be otherwise compromised such as by an inability to implement satisfactory controls in the herd. Any herds restricted longer than 18-months and continuing to produce TB-infected reactors must be considered for depopulation. Where herd depopulation has been deemed necessary the final decision will be made in consultation with the Regional SSVI. The SVI and RSSVI will determine the appropriate rest period for the land usually a minimum of four months during which the keeper may not restock or have cattle on the land. The agreed period will determine the depopulation payment made and cannot be subsequently amended. Thus if there is some reason why a shorter period would be acceptable (e.g. depopulation prior to or at the end of the housing period so that grazing land has effectively been left fallow for 4-months before stock go out to it) this must be considered and agreed prior to depopulation as should the cleansing, disinfection, any refurbishment of areas where effective cleansing and disinfection is not possible, any fencing (boundaries, badger setts/latrines and/or stagnant water etc.) that has not already been done during the restriction. Further, unless badgers have been excluded as a cause of the outbreak a badger capture programme must be conducted and a programme of testing undertaken in contiguous herds prior to restocking. See also section 18 Wildlife Policy.

Kaplan-Meier survival estimates for time to restriction following depopulation by reason-risk for depopulation and prior risk of bTB.

![Kaplan-Meier survival estimates](image)

Note: Herds which have been depopulated may revert to ‘D’ classification going forward following restocking when at least one series of badger capture has been completed. A post-depopulation check test should be conducted as soon as practicable once restocking is substantially completed or 4-months post commencement whichever is first. Analysis has shown that this test is positive in ~5-7% of herds and ordinarily identifies animals that were infected in the herd of origin (i.e. introduced/bought-in) thus their prompt identification and removal is desirable.

Where an infected group of cattle is present the appropriate response may be to confine (ER84) the group to a specific location (see below) or possibly to remove the entire group, ‘identified’, as reactors. If the infected group is a discrete stand-alone entity (separately grazed/housed/tested) within the herd, with no contact with the remainder of the otherwise clear herd, then an application for a partial depopulation, with attendant grant eligibility may be made to the SVI. If the SVI considers that the application has merit it will be referred to the regional SSVI for decision. Please note that eligibility for a partial depopulation effectively accepts that this section of the herd is epidemiologically distinct and eligible for a separate herd number it also requires that the depopulated section of the holding remains free of cattle for the depopulation period in the same manner as if a full depopulation had occurred and under the TB Regulations, a formal direction of such should issue. As long as the purpose is to prevent the spread of
tuberculosis the VI may direct the keeper under Regulation 28(1) that movement is not allowed (See SI 58/2015 Appendix 1c)

Further cleansing and disinfection, a contiguous herd testing programme, refurbishment, fencing etc. and a badger removal programme should also operate as if a full herd depopulation had occurred. A separate herd number should be issued for the depopulated section post derestriction

17. Private (Movement) Test & export-test certification.

In their annual instructions PVPs are informed, that, “Any tuberculin test may only be conducted with the approval of a Veterinary Inspector”. This is provided for in S.I. No. 58 of 2015; A person authorised under section 37(1) of the Act for the purposes of section 38(1) in relation to the testing for bovine tuberculosis in ruminants shall conduct a test in accordance with these Regulations and any terms and conditions determined by the Minister. Thus, a veterinary practitioner must have individual test approval, before commencing a pre-movement test or a post-movement test for TB (so called Private test) which are recommended particularly for breeding animals prior to entering the main herd. Test approval will not be given for animals in herds, which have not had a herd test within the previous twelve months or in herds trade restricted while awaiting completion of a TT7 or TT8. In such cases the herd test will be brought forward where requested. When assessing whether private test approval should issue for a particular herd the Veterinary Inspector must assess whether there is epidemiological information available to establish a likelihood of exposure to infection. If such a likelihood of exposure to infection is identified, then approval to conduct a private tuberculin test must be refused and the listing or advancement of a herd test must be considered. Thus, the status of contiguous herds, any trace back information, presence of an inconclusive TB reactor, herd history, next test type scheduled and date that it is due have all to be considered. Private test approval for inter-herd/export movement as opposed to movement to slaughter should not issue when a herd test is already “Awaiting Itinerary”.

An advance itinerary (ER9) must be submitted for Private tests arranged by the PVP in advance of each private TB test. The minimum test interval for a pre-movement tuberculin test for intra-community trade in bovine animals is 42 days. Thus PVPs have been informed that export certification will not issue for an animal following a tuberculin test where the animal was also tuberculin tested within the previous 42 days. This applies equally to animals tested in the course of a herd test. (See ER4 appendix 2).

Integration of AHCS test information by AIM ensures that ineligible animals are not exported.

18. Wildlife Policy

DAFF’s wildlife policy is primarily driven by epidemiological investigation and the completion of an ER76B following a ‘H’-type breakdown (see section 6). In herds where 3 or more reactors have been disclosed and badgers are implicated as the probable/likely cause a request for a badger survey will be submitted by the RVO SVI via AHCS.

There will also be occasions where SVIs will schedule herds other than ‘H’ type breakdowns for ER76B type investigations in response to a atypical breakdown, an area problem, multiple reactor or lesion trace-back, or other local problems. In the context of the wildlife policy the principle objective of the ER76B investigation is to establish firstly if the breakdown was due to M. bovis and then if an introduced or residually infected animal was the likely source of the breakdown? If not, did the investigation detect badger signs in the local environment of the herd such that a local survey for badger habitats is warranted? Following this survey, the locations of any setts identified are computerised on DAFM’s GIS databases and where warranted, badgers are removed under a licence granted by the Parks and Wildlife division of the Department of Environment, Heritage & Local Government, who as the name suggests are responsible for all wildlife matters.

Once a badger sett is assigned to a treatment area for capturing, it will continue to be monitored for signs of re-population and where this occurs re-captures will be undertaken.

The VI conducting an ER76B epidemiological investigation will assess the security of feedstores to prevent access by livestock, vermin or wildlife; that feed and water troughs are not accessible by wildlife; that meals/minerals/supplements are not being fed to wildlife by feeding cattle close to hedges and such and that
appropriate rodent control measures are in place. The VI should also point out setts and badger latrines from which cattle should be excluded (fence out) and the need to check pasture for dead/dying or moribund badgers before releasing cattle into pastures.

It is acknowledged that the *M. bovis* transmission pathways between wildlife and cattle are not well understood. Normal badgers may avoid cattle at pasture and not routinely enter buildings but the same may not be true of badgers clinically ill with TB whose normal movement and behaviour around cattle has not been studied for obvious reasons. Nevertheless, the primary spread of disease appears relatively unlikely to happen as a result of direct contact either at pasture or by infected but apparently healthy badgers coming into cattle sheds and contacting cattle directly. It is certain however, that multiple possible pathways exist ranging from contact between livestock and dead or dying badgers, perhaps behaving abnormally, to environmental contamination from discharges or excretions. Clifton Hadley et al., in 1993 reported that infected badgers may intermittently shed *M. bovis* in sputum, faeces and urine although there is generally a lack of information on the distribution and magnitude of environmental reservoirs of *M. bovis*. In 2016 French researchers reported finding environmental samples positive for the presence of *M. bovis* strains in the environment of farms affected by bovine TB in a restricted area within the Côte d’Or region where shared genotypes of *M. bovis* circulate in a multi-host system including cattle, badgers, wild boar and deer. The persistence of detection over an eight month-period, despite an absence of the supposed source of infection, suggested that the DNA detected could belong to persistent viable cells. The detection of positive signals in 10% of water samples from naturally occurring water springs and accompanying flowing water in pastures where both cattle and wildlife had access is supportive of a role for water in environmental dissemination and in animal contamination perhaps even by the formation and inhalation of bioaerosols. The highest prevalence detected amongst 356 environmental samples assessed were in badger sett soil and badger latrines averaging 7.3% and 7% respectively. Similar work in the U.K. using qPCR assay of faecal samples from badger latrines and individual or combined diagnostic test results from trapped badgers suggested that spring was the optimum latrine sampling period, with autumn an acceptable confirmational back up with 100% and 80% sensitivity respectively. The study demonstrated that badger faecal contamination may create potential infection hotspots with a substantial and a seasonally variable environmental reservoir that may be responsible for a proportion of transmission amongst badgers and onwards to cattle. Summer had the highest detected shedding rates of *M. bovis* from badgers overall and summer would also have the highest rates of cattle presence on pasture. Research at Warwick University, with qPCR of faeces and culture performed in parallel on samples taken from badgers in areas in the Republic of Ireland with high levels of TB breakdown in cattle, indicates that faecal shedding by badgers is a good proxy for respiratory shedding. Again in France Payne and others monitored wildlife visits to facilities on 25 farms i.e. 101 water and food access points located in pastures and farm buildings over the course of a year using camera traps in a bTB infected area. The frequency of visits from red deer was highest at salt licks and in summer. Badger were found to be more frequent in winter and on pasture feed troughs. Their results highlight the wide variation in the patterns of contact at the wildlife-cattle interface.


among the different bTB-susceptible species. Bearing in mind that Ghodbane et al (2014) demonstrated that M. bovis can be cultured from mice fed soil in which M. bovis had been persisting for months, thus demonstrating the viability of M. bovis over a prolonged period, it is probable that pasture contaminated with M. bovis shed by badgers may remain a source of infection to cattle and other susceptible species for quite some time. Fencing off badger setts, spoil heaps and latrines to prevent access by cattle is both possible and recommended to reduce the risk of infection in cattle. Farmers should also be advised to raise water-troughs and not to feed or to provide cattle with minerals or other supplements at grass and particularly not adjacent to hedgerows where these can be easily accessed by wildlife. However, it is not possible for farmers to exclude access to pasture by badgers and, at this time, no satisfactory biosecurity measure is available to farmers to prevent exposure of cattle to this potential source of infection at pasture.

The long-term aim of DAFM’s wildlife policy is to administer an oral BCG vaccine to badgers, sufficient to achieve and maintain a high degree of population immunity thus rendering the species less susceptible to spreading and/or becoming infected with M. bovis and thus less likely to be a source of infection for cattle locally. The current Wildlife policy is designed to reduce the density of infected badgers in areas where TB has been identified in cattle herds, to record data on the location of setts and to prepare badgers in areas previously affected with TB for vaccination with BCG. A large-scale field trial in County Kilkenny was completed 2013, up to 1,000 badgers were recruited to the study and allocated to different zones, whereby they were vaccinated with BCG or placebo. Treatment of badgers continued for three years. The outcome of interest was incident cases of tuberculosis as measured by serological responses and severity of disease at post-mortem. The field work of this trial is completed, the report and the report of findings and outcomes are expected in 2016/17. Preliminary analysis indicates a positive outcome of the trial with a decrease in serologically positive badgers and clinical disease levels in zones with 100% oral vaccination. In anticipation of this outcome a non-inferiority trial where intramuscular vaccination of badgers is being evaluated as a substitute for continued culling of badgers is running in six counties (Cork, Galway, Longford, Monaghan, Tipperary and Waterford) since 2014 and is planned to end in 2017. Assuming vaccination can be substituted for the present culling strategy, the change over from culling to the equally resource demanding injectable BCG vaccination, initially, will likely commence in 2018 with a view to replacing this ultimately with an oral vaccination programme, if and when, such a vaccine is available. Culling may still have to continue in TB hot spots to protect both cattle and wildlife.

Depopulated herds (Section 16): Unless the cause of the breakdown has been conclusively identified as non-badger related an application for a capture block should normally be made. This block should be serviced every 3-4 months for 18 months after depopulation (full or partial), before reverting to normal capture cycles, so that the restocked herd is protected from breakdown to the maximum possible extent.

Badgers reported dead or dying by farmers or other members of the public should normally be disposed of via the same route as badgers captured by the Department but not be specifically selected for post-mortem examination. However, where such badgers have been reported as dying in a field or shed where cattle are located then they should, if fresh, be submitted immediately for post-mortem examination. If suspect-positive for TB the holding on which they were found should be restricted while awaiting confirmation and a TB test conducted a minimum of 42 days post contact with the dying/dead TB-positive badger.

SVI/VIs should monitor wildlife controls and activities in their areas of responsibility on Ezone where the Wildlife unit software can be accessed; http://ezone/intranet/businessareas/wildlifeunit/

The role of deer as a maintenance host for M. bovis in Ireland and their role in seeding infection into cattle herds is less clear. While deer, in common with all other mammalian species, including humans, may become infected with TB the International view is that they rarely act as an independent maintenance host causing spill back to cattle herds. An exception to this is the state of Michigan USA where, having been TB-free for a number of years, in 1994 they detected cattle infected by M. bovis, and it became recognized that they had a TB problem in wild white-tailed deer. A total of 65,000 free-ranging deer were tested, and 340 were found to be M. bovis positive. The disease was also found in other wildlife species. The situation was unique in that there had never been reports of self-sustaining bovine TB in a wild, free-ranging cervid population in North America. Scientists, biologists, epidemiologists, and veterinarians who studied this situation concluded that the most logical theory is that high deer densities and the focal concentration caused by baiting (the practice of hunting deer by enticement to feed) and autumn/winter feeding of deer

are the factors most likely responsible for the establishment of self-sustaining TB in free-ranging Michigan
deer. Baiting and feeding have been banned since 1998 in counties where the disease has been found. In
addition, the deer herd has been reduced by 50% in the endemic area. The measures of apparent TB
prevalence have been decreased by half between 1997 and 2001, providing hopeful preliminary evidence
that TB eradication strategies for deer were succeeding.  

A study of the historical factors influencing the occurrence and distribution of M. bovis infection among
wildlife in Michigan found that high deer numbers and severe winter feed shortages, resulting from habitat
destruction in the area in 1930, contributed to the transmission of tuberculosis from cattle to deer in that
period. Starvation had increased the susceptibility of deer to infection and modified behaviour such that
exposure to infected cattle was increased. Ribotyping of M bovis from a human patient (note that humans
i.e. deer hunters also had become infected from TB infected deer) suggests that the strain of M. bovis
presently infecting white-tailed deer in the region is the same strain that affected cattle farms at that earlier
time. The study concluded that feeding deer to maintain numbers above the normal carrying capacity of the
area led to deer depending on consumption of livestock feed for survival during winter and increased
contact with domestic cattle. They further recommended that this practice should be avoided. 

Wicklow is the only county in Ireland where annually TB has been confirmed in multiple deer for many
years. Wicklow has had a problem with high bTB prevalence in cattle dating back to the 1970s. This had
resulted in the deployment of the TB veterinary task-force to test cattle herds in both East and West
Wicklow in the 1970s and a further project area being established in South West Wicklow in the early
1980s to focus on cattle TB. Herd and animal TB incidence would fall when controls intensified only to re-
emerge. Undoubtedly badgers play a role in this re-emergence and a number of small scale studies have
been conducted to investigate the role of deer. In 2007/8 a total of 80 feral deer were culled within three
specifically defined areas of East Wicklow and South County Dublin. In addition to the culled deer a total
of 27 carcases or part carcases were submitted by hunters. Sixty-eight badgers culled from the three areas
and 73 tuberculin test reactor cattle were included in the study. M. bovis infection was identified in both
wildlife species and isolated from 18 (26.5%) of 68 badgers examined and from 4 (5%) of 80 deer
examined. Animals with generalised disease and with pulmonary lesions were identified in both species.
All cervine and badger isolates belonged to just 3 strains, two of which were closely related and accounted
for 100% of cervine isolates, 82% of badger isolates and isolates from 67% of bovine herds. The detection
of a strain type that is common to each of three host species is strong evidence of inter-species transmission.
This implies that M. bovis infection in the two wildlife species are inter-related rather than independent of
each other. However, the predominant direction of inter-species transmission remains undetermined  

19. Movement into and out of a restricted herd

By EU law (Appendix 1b) animals may not be moved into a TB restricted holding except following one
clear test AFTER the infected animal has left the holding. A ‘move-in’ application may be considered
following a clear reactor retest (or clear factory lesion retest or clear TT10) conducted after the infected
animal has left the herd and where appropriate risk mitigation measures are agreed, where the prohibition
on buying in would not allow the holding to function as a commercial entity and where, following
epidemiological assessment, it has been determined that there is no discernible monetary risk to the
National Exchequer or EU budget (Directive 78/51).

31 Miller R, Kaneene JB. (2006) Evaluation of historical factors influencing the occurrence and distribution of
32 William Byrne, Teresa MacWhite, Jim Egan, Ann Sharpe, Colm Brady, Joanne McLerno and Eamonn Costello. A
study of Tuberculosis of wildlife and cattle in East Co. Wicklow and south Co. Dublin. Unpublished
There are a number of exceptions to the general inward movement prohibition provided for in Circular ER01/14:

i. **Newly established herds** – procedures that allow such herds to acquire stock and to ensure that the herd is then tested in order to acquire a genuine OTF status (covered by Circular ER18/07).

ii. Introduction of a **replacement stock bull(s)** to facilitate normal herd function is catered for by an ER37A permit. A 30 day pre-movement test is required; otherwise entitlement to compensation is forfeited.

iii. **Emergency replacement suckler calf** (on welfare grounds -where a calf to a suckler cow dies) notified to NBAS on Form NBAS 31F catered for by an ER37A permit.

iv. Movement into a TB-free (OTF) herd with trading status restricted pending 1<sup>st</sup> post-derestriction test (TT7) or because it is **contiguous to** infected fragments of a **high risk disease breakdown** (TT8).

v. Movement to/from a restricted herd may occasionally be permitted in exceptional circumstances so as to alleviate or prevent a welfare problem. For instance, movement of ‘test negative’ animals, from a B&B, or a (contract) rearing/grazing/feeding herd, or a registered/unregistered farm ‘partner’/family member’s holding with a separate herdnumber with attendant restriction, as per Directive 64/432/EEC criteria, of the erstwhile OTF herd if relevant. To be eligible for permission and exempted from the normal conditions pertaining to compensation, in the event of further reactors, a case must be made and submitted (word document attached to e-mail) to HQ (SSVI and/or ERAD AP) outlining why the move is necessary for the welfare of the animals involved (e.g. heavy in calf and no calving/milking facilities in the ‘rearing’ location or no calf rearing facilities in the birth herd) and indicating the risk mitigation measures (e.g. isolation, separate management from other milkers incorporating disinfection etc.) that have been agreed. This type of permit is catered for by an ER37X application. A 30-day pre-movement test is required; for any animals moving when >6-weeks of age, otherwise entitlement to compensation is forfeited.

**Movement into Feedlot herds:**

A Feedlot herd is a specialised finisher of beef that does not deliberately engage in the active breeding of animals, notwithstanding that an occasional cow/heifer may calve because it was pregnant on arrival to the feedlot, and meets the criteria in Circular ER 10/2013 – revised. Usually a TB restriction/diagnosis in a feedlot herd is due to an animal having acquired infection elsewhere and disclosing as TB positive at slaughter or test without evidence of TB spread in the feedlot herd. However, the first principle remains not to introduce animals into a situation where an active TB outbreak is or may be ongoing and there is consequent risk of any introduced animals acquiring infection and to minimise the possibility of onward spread of TB. At a minimum a desktop/database epidemiological evaluation of the disease pattern exhibited in the herd must be constantly monitored including when the herd first becomes restricted. When the extent and nature of the TB problem has been ascertained and, if necessary following a test to identify and remove any further infected animals and where within herd spread of infection is considered unlikely a permit to continue to acquire animals for finishing may be given (subject to the conditions laid down in the circular).

**20. Survival of M. bovis**

Depending on when, where and under what conditions the research has been conducted, various survival times are reported in the literature. Thus the early work, done when TB was generally far advanced in an animal before it was suspected, suggested that *M. bovis* is a highly resistant organism surviving in cow faeces for at least 5 months in winter, 4 months in autumn, 2 months in summer and in soil for up to 2 years; 4 months in liquid manure stored underground and for 1-2 months in soil during the summer months (Williams and Hoy, 1930). Maddock (1933) reported that direct sunlight killed bacilli in cultures within a few hours whereas bacilli present in pus and “morbid discharges” may remain viable for several weeks. In summer months in England, *M. bovis* could not be recovered from grass contaminated with infected badger urine after 3 days or from naturally infected badger faeces after periods of 1 or 2 weeks. The activity of sunlight and of other bacteria, protozoa and fungi, which normally contribute to the breakdown of faeces, appears to destroy *M. bovis*. Similarly, the decomposition of a carcase will destroy *M. bovis*. In a carcase left on pasture, the level of infection had dropped sharply after 2 weeks and after 4 weeks *M. bovis* could not be recovered. In 3 buried badger carcases, *M. bovis* could not be recovered after 2, 3 and 6 weeks respectively. (Third Report MAFF, London, 1979). Other times quoted are summarised below.
**M. bovis** survival in a variety of conditions as reported in the literature.

<table>
<thead>
<tr>
<th>Sample</th>
<th>Condition</th>
<th>Survival</th>
<th>Author</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cattle faeces</td>
<td>Summer - open jar</td>
<td>152-178 days</td>
<td>Maddock 1933</td>
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<tr>
<td></td>
<td>Exposed grassland</td>
<td>56 days</td>
<td>Reuss 1955</td>
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<tr>
<td></td>
<td>Shade in sealed flask 16-18°C</td>
<td>12 weeks</td>
<td>Zorawski <em>et al.</em>, 1978</td>
</tr>
<tr>
<td></td>
<td>Sunlight 27.5°C</td>
<td>37 days</td>
<td>Vera &amp; Volkovsky 1980</td>
</tr>
<tr>
<td></td>
<td>Shade 27.5°C</td>
<td>71 days</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Lab. 2-4°C</td>
<td>&gt;135 days</td>
<td>Duffield &amp; Young 1985</td>
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<tr>
<td>Solid manure</td>
<td></td>
<td>790 days</td>
<td>Turgenbaev 1989</td>
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<tr>
<td>Grass</td>
<td>Summer</td>
<td>49 days</td>
<td>Maddock 1933</td>
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<tr>
<td></td>
<td>Autumn</td>
<td>63 days</td>
<td>Maddock 1934</td>
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<tr>
<td>Pasture</td>
<td>Summer</td>
<td>4 days (max)</td>
<td>Jackson (N.Z.) 1995</td>
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<tr>
<td></td>
<td>Winter</td>
<td>7 days</td>
<td></td>
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<tr>
<td>Crop</td>
<td>Contaminated Sewage</td>
<td>35 days</td>
<td>Donsel &amp; Larkin 1977</td>
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<tr>
<td>Dust</td>
<td></td>
<td>90-120 days</td>
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<tr>
<td>Clothing</td>
<td></td>
<td>45 days</td>
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<tr>
<td>Sputum</td>
<td>Cool, dark location</td>
<td>6-8 months</td>
<td></td>
</tr>
<tr>
<td>Water</td>
<td>Spring/Summer</td>
<td>20 days (max)</td>
<td>Fine (Michigan) 2011</td>
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<tr>
<td></td>
<td>Winter/Summer</td>
<td>21 days (max)</td>
<td></td>
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<tr>
<td>Hay</td>
<td>Spring/Summer</td>
<td>3 days (max)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Winter/Summer</td>
<td>42 days (max)</td>
<td></td>
</tr>
<tr>
<td>Soil</td>
<td>Spring/Summer</td>
<td>11 days(max)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Winter/Summer</td>
<td>88 days (max)</td>
<td></td>
</tr>
<tr>
<td>Cheese – made with raw milk containing <em>M. bovis</em></td>
<td>The inoculation level is not given for most of the experiments in the reference</td>
<td>M. bovis detectable after</td>
<td>Collection of data from Spahr and Schafroth 2001 (Appl. Env. Microbiol. 67, 4199-4205)</td>
</tr>
<tr>
<td>Camembert</td>
<td></td>
<td>180 days</td>
<td></td>
</tr>
<tr>
<td>Cheddar</td>
<td></td>
<td>220 days</td>
<td></td>
</tr>
<tr>
<td>Camembert</td>
<td></td>
<td>60 days</td>
<td></td>
</tr>
<tr>
<td>Edam</td>
<td></td>
<td>60 days</td>
<td></td>
</tr>
<tr>
<td>Bulgarian White</td>
<td></td>
<td>120 days</td>
<td></td>
</tr>
<tr>
<td>Swiss Emmental</td>
<td>Both types of cheese are manufactured from naturally infected milk with 1-10 cfu/ml</td>
<td>5 days (not after 22 days)</td>
<td></td>
</tr>
<tr>
<td>Gruyere</td>
<td></td>
<td>22 days(not after 31 days)</td>
<td></td>
</tr>
<tr>
<td>Swiss Tilsiter</td>
<td></td>
<td>305 days</td>
<td></td>
</tr>
<tr>
<td>Camembert</td>
<td></td>
<td>47 days</td>
<td></td>
</tr>
<tr>
<td>Emmental</td>
<td>Infection of guinea pigs possible after 90-days</td>
<td>90 days</td>
<td></td>
</tr>
<tr>
<td>Blue</td>
<td></td>
<td>90-120 days</td>
<td></td>
</tr>
</tbody>
</table>
The recorded persistence of *M. Bovis* in the Michigan environment under natural weather conditions strongly suggests the contribution of indirect means to the transmission of bovine TB. However, survival studies in New Zealand showed a relatively short period of survival of *M. Bovis* outside the hosts and concludes that environmental contamination of pasture may be relatively unimportant in the epidemiology of tuberculosis in cattle. In 2016 French researchers reported finding environmental samples positive for the presence of *M. bovis* strains in the environment of farms affected by bovine TB in a restricted area within the Côte d’Or region where shared genotypes of *M. bovis* circulate in a multi-host system including cattle, badgers, wild boar and deer. The persistence of detection over an eight month-period, despite absence of the supposed source of infection, suggested that the DNA detected could belong to viable cells. The detection of positive signals in 10% of water samples from naturally occurring water springs and accompanying flowing water in pastures where both cattle and wildlife had access is supportive of a role for water in environmental dissemination and in animal contamination perhaps even by the formation and inhalation of bioaerosols. The highest prevalence detected amongst 356 environmental samples assessed were in badger sett soil and badger latrines averaging 7.3% and 7% respectively.

### 21. Cleansing and Disinfection

Disinfection means the application, after thorough cleansing, of procedures and/or chemicals intended to destroy the infectious or parasitic agents of animal diseases, including zoonoses; this applies to premises, vehicles and different objects which may have been directly or indirectly contaminated (OIE manual).

Instructions to keepers regarding cleansing and disinfection are generally straightforward, clear and reflect a differentiation in approach at individual farm level based on assessed risk consistent with overall disease control objectives. The controls applied to ensure compliance – which include elements of keeper declaration and field inspection – are also risk based as envisaged in Regulation (EU) No 882/2004.

DAFM has a list of approved disinfectants to be used in a variety of animal disease situations. This composite list is made available to operators of markets, farmers/keepers and it is absolutely clear from the list which disinfectants are approved for which disease and the appropriate dilution rates. In the context of a TB outbreak, the appropriate disinfectants effective against TB are clearly identifiable.

The restriction notice (ER 22) specifies and legally requires that, where all the reactor animals on a holding "are removed from the holding, all houses used for housing animals and all pens, fittings and receptacles used for animals are forthwith cleansed and disinfected". Hence farmers are instructed (ER24) to carry out the cleaning and disinfection immediately after the removal of reactor animals within a specified time frame. When the notice is served on the keeper the Veterinary Inspector will take into consideration an interval that will normally fall beyond the date of removal of any animals. In addition, the ER26X which is signed by the farmer when reactors are being removed says "(f) the premises used for housing the animals and any other areas specified must be cleansed and disinfected to the satisfaction of the RVO after removal of the reactor(s) described on Permit(s) ER26". An extension may be allowed when cattle are housed for the winter as they cannot be moved out to allow thorough cleansing and disinfection. (ER64). RVOs should be cautious of acceding to requests to postpone cleansing and disinfection when stock are not housed and need to ensure that it is completed before either additional stock are moved in or OTF status is restored.

The restriction notice also instructs the farmer that “any manure and slurry on the holding is stored for at least two months prior to being moved off or spread on the holding;” The restriction notice and the ER 26X also requires that "receptacles containing an approved disinfectant are placed at any entrance to or exit from the environment sampled. The provision of disinfectant at this time is necessary to protect the environment which may otherwise become contaminated by material from the holding. It is essential that the disinfectant is effective against the disease for which the premise is being disinfected. In a TB outbreak, the appropriate disinfectants effective against TB are clearly identifiable.


the holding or any animal housing thereon.” With regard to the re-testing, given that the restriction notice provides for immediate cleansing and disinfection, this would ordinarily be completed prior to the first retest due at 60-day interval, except as provided for in ER64 where stock are housed and it is not possible to vacate the housing to conduct the cleansing and disinfection.

The ER 24 provides for circumstances where a veterinary inspector has, following assessment of the herd breakdown, determined that the disease is confined to a part or parts of the holding such that disinfection of specific parts of the holding and/or grazing restriction of part of the holding shall be deemed to be sufficient. Thus the ER24 covers situations where the conditions specified by the ER22 are varied. It is provided for in the legislation that a veterinary inspector authorised under that legislation may attach conditions to a notice issued under that legislation and thus a veterinary inspector may also vary a condition on a notice.

Detailed advice for the handling of manure being moved from sheds is provided in the ER24 and includes the requirement that “before removal of the manure, be sprayed or saturated with an approved disinfectant”. Since no disinfectant would be capable of killing *M. bovis* by this procedure, its purpose is merely to prevent aerosolisation of any infective organisms, which might pose a risk to the humans moving the manure.

DAFM does not visit every farm to supervise cleaning and disinfection and, although individual farms may require supervision following a risk assessment, does not believe this is generally required. Herd keepers are required to confirm to DAFM that they have completed cleaning and disinfection (ER64A). These declarations are then subject to official follow up controls (percentage based on risk and random selection) so as to ensure compliance with EU requirements. Where organic material remains evident on inspection primary cleansing is clearly unsatisfactory and must be repeated before disinfection application and before compliance with requirements can be deemed satisfactory.

22. Desktop Resources

**Ezone**
Access to ERAD Intranet. By clicking on “Business Areas” on the top bar of the screen, navigate to the “ERAD” area [http://ezone/intranet/businessareas/eraddivision/](http://ezone/intranet/businessareas/eraddivision/) where the ERAD circulars including the subject index list for ERAD circulars and Forms may be accessed under “Circulars”.

**Herdfinder**
Contiguous Herd Enquiry or Herdfinder is accessed on the main screen of the Ezone- lower left hand side. Herdfinder can also be accessed by typing “HF” on the address bar of the Ezone. A help section is also available on Herdfinder – see main Herdfinder page. The help section is a series of training videos that instruct users on how to do various tasks and can be viewed as many times as desired. The videos will be updated from time to time and as any new features and functions of Herdfinder become available. If you cannot ‘see’ the video on your PC because the correct software is not installed – click on the appropriate link and an e-mail will be sent to ISD who will in turn install the correct software to allow you to ‘view’ the video on your PC.

Please enter herd no. including check digit of herd and follow on screen instructions. This Web programme is simple to use and additional training is available from time to time.

You can also search for named individuals and confine it to RVO areas using the name and address search. You can get X and Y co-ordinates and Latitude and Longitude values as well as mapping several chosen herds on the suite of programmes available on the Herdfinder site.

**Wildlife unit**
WU software can be accessed via the ‘Business Area’ on Ezone main screen [http://ezone/intranet/businessareas/wildlifeunit/](http://ezone/intranet/businessareas/wildlifeunit/)

**Library** (also a “Business Area” on main screen) [http://ezone/intranet/businessareas/#L](http://ezone/intranet/businessareas/#L)
(it appears that much of this site is not being kept up to date unless linking to an outside body)

-Legal resources – access to the Irish Legal Information Initiative - ILII -Run by UCC Law Faculty giving legislation updates and case law.

OJ Online - don’t forget to logoff when finished
Online journals and articles including Search facility for abstracts of the research literature

**Vetzone** – This area is now available under “Business Areas” and “Veterinary Service”  
http://ezone/intranet/businessareas/veterinaryservices/ on the Ezone and includes a link to CVERA

**Irish legislation** - http://www.irishstatutebook.ie/


**Single Sign On System.**  
This is the Departments strategic platform and contains the area where AIM (Animal Identification and Movement), AHCS (Animal Health Computer System) and iMap are located. Log-Ins are arranged locally through the Corporate Customer System (CCS).
APPENDIX 1

Directive 64/432/EEC

ANNEX A

ANNEX A (98/46/EC)

1. Officially tuberculosis-free bovine herd

For the purposes of this section ‘bovine animals’ means all bovine animals with the exception of animals taking part in cultural or sporting events.

1. A bovine herd is officially tuberculosis-free if:

(a) all the animals are free from clinical signs of tuberculosis;

(b) all the bovine animals over six weeks old have reacted negatively to at least two official intradermal tuberculin tests carried out in accordance with Annex B. the first six months after the elimination of any infection from the herd and the second six months later or where the herd has been assembled solely from animals that originate in officially tuberculosis-free herds. The first test shall be carried out at least 60 days after assembly and the second shall not be required;

(c) following the completion of the first test referred to in (b), no bovine animal over six weeks old has been introduced into the herd unless it has reacted negatively to an intradermal tuberculin test performed and assessed according to Annex B and carried out either in the 30 days prior to, or the 30 days after the date of its introduction into the herd; in the latter case the animal(s) must be isolated physically from the other animals of the herd in a way to avoid any direct or indirect contact with the other animals until proven negative.

However, the competent authority may not require this test to be carried out for movements of animals on its own territory if the animal is from an officially tuberculosis-free herd, except in a Member State where, on 1 January 1998 and until the status of officially tuberculosis-free region is obtained. the competent authority required such tests to be carried out for animals moving between herds participating in a network system as referred to in Article 14.

2. A bovine herd will retain officially tuberculosis-free status if:

(a) the conditions detailed in 1 (a) and (c) continue to apply;

(b) all animals entering the holding come from herds of officially tuberculosis-free status;

(c) all animals on the holding, with the exception of calves under six weeks old which were born in the holding, are subjected to routine tuberculin testing in accordance with Annex B at yearly intervals.

However the competent authority of a Member State may, for the Member State or part of the Member State where all the bovine herds are subject to an official programme to combat tuberculosis alter the frequency of the routine tests as follows:

- if the average determined at 31 December of each year of the annual percentages of bovine herds confirmed as infected with tuberculosis is not more than 1% of all herds within the defined area during the two most recent annual supervisory periods the interval between routine herd tests may be increased to two years and male animals for fattening within an isolated epidemiological unit may be exempted from tuberculin testing provided that they come from officially tuberculosis-free herds and that the competent authority guarantees that the males for fattening will not be used for breeding and will go direct for slaughter.

- if the average determined at 31 December of each year of the annual percentages of bovine herds confirmed as infected with tuberculosis is not more than 0.2% of all herds within the defined area during
the two most recent biennial supervisory periods. The interval between routine tests may be increased to three years and/or the age at which animals have to undergo these tests may be increased to 24 months.

- If the average determined at 31 December of each year of the annual percentages of bovine herds confirmed as infected with tuberculosis is not more than 0.1% of all herds within the defined area during the two most recent supervisory triennial periods the interval between routine tests may be increased to four years, or, providing the following conditions are met, the competent authority may dispense with tuberculin testing of the herds:
  1. Before the introduction into the herd all the bovine animals are subjected to an intra-dermal tuberculin test with negative results; or
  2. All bovine animals slaughtered are examined for lesions of tuberculosis and any such lesions are submitted to histopathological and bacteriological examination for evidence of tuberculosis.

The competent authority may also in respect of the Member State or a part thereof, increase the frequency of tuberculin testing if the level of the disease has increased.

3A. The officially tuberculosis-free status of a herd is to be suspended if:

(a) the conditions detailed in paragraph 2 are no longer fulfilled; or

(b) one or more animals are deemed to have given a positive reaction to a tuberculin test, or a case of tuberculosis is suspected at post-mortem examination. When an animal is considered to be a positive reactor it will be removed from the herd and slaughtered. Appropriate post-mortem, laboratory and epidemiological examinations shall be carried out on the positive reactor or the carcass of the suspect animal. The status of the herd will remain suspended until such time as all laboratory examinations have been completed. If the presence of tuberculosis is not confirmed, the suspension of the officially tuberculosis-free status may be lifted following a test of all animals over six weeks of age with negative results at least 42 days after the removal of the reactor animal(s); or

(c) the herd contains animals of unresolved status as described in Annex B. In this case, the status of the herd is to remain suspended until the animals' status has been clarified. Such animals must be isolated from the other animals of the herd until their status has been clarified, either by a further test after 42 days or by post-mortem and laboratory examination;

(d) however, by way of derogation from the requirements of paragraph (c), in a Member State where the competent authority carries out routine herd testing using the comparative tuberculin test described in Annex B, and in the case of a herd where no confirmed reactor animals have been disclosed for at least three years, the competent authority may decide not to restrict the movement of other animals in the herd, provided that the status of any inconclusive reactor is resolved by a further test after 42 days and that no animals from the holding are allowed to enter into intra-Community trade until the status of any inconclusive reactor has been resolved. If at this further test any animal either gives a positive reaction or continues to give an inconclusive reactor reaction, then the conditions of paragraph (b) apply. If the presence of disease is subsequently confirmed, all animals leaving the holding since the time of the last clear herd test must be traced and tested.

3B. The officially tuberculosis-free status of the herd is to be withdrawn if the presence of tuberculosis is confirmed by the isolation of *M. bovis* on laboratory examination.

The competent authority may withdraw status if:

(a) the conditions detailed in point 2 are no longer fulfilled. or

(b) classical lesions of tuberculosis are seen at post-mortem examination. or

(c) an epidemiological enquiry establishes the likelihood of infection.

(d) or for any other reasons considered necessary for the purpose of controlling bovine tuberculosis.

Tracing and checking is to be undertaken by the competent authority of any herd considered to be epidemiologically related. The officially tuberculosis-free status of a herd is to remain withdrawn until cleansing and disinfection of the premises and utensils has been completed and all animals over six weeks of age have reacted negatively to at least two consecutive tuberculin tests, the first no less than 60 days and
the second no less than four months and no more than 12 months after the removal of the last positive reactor.

4. On the basis of information supplied in accordance with Article 8, a Member State or part of a Member State may be declared officially tuberculosis-free according to the procedure laid down in Article 17 if it meets the following conditions:

(a) the percentage of bovine herds confirmed as infected with tuberculosis has not exceeded 0.1% per year of all herds for six consecutive years and at least 99.9% of herds have achieved officially tuberculosis-free status each year for six consecutive years the calculation of this latter percentage to take place on 31 December each calendar year;

(b) each bovine animal is identified in accordance with Community legislation, and

(c) all bovine animals slaughtered are subjected to an official post-mortem examination;

(d) the procedures for suspension and withdrawal of officially tuberculosis-free status are complied with.

5. The Member State or part of a Member State will retain officially tuberculosis-free status if the conditions 4(a) to (d) continue to be met. However, if there is evidence of a significant change in the situation as regards tuberculosis in a Member State or part of a Member State which has been recognised as officially tuberculosis-free, the Commission may, in accordance with the procedure laid down in Article 17, take a Decision suspending or revoking the status until the requirements of the Decision have been fulfilled.

ANNEX B

TUBERCULOSIS

1. IDENTIFICATION OF THE AGENT

The presence of *Mycobacterium bovis* (M. bovis), agent of bovine tuberculosis, in clinical and post-mortem specimens may be demonstrated by examination of stained smears or immunoperoxidase techniques and confirmed by cultivation of the organism on primary isolation medium.

Pathological material for the confirmation of M. bovis should be taken from abnormal lymph nodes and parenchymatous organs such as lungs, liver, spleen, etc. In the cases where the animal does not present pathological lesions samples from the retropharyngeal, bronchial, mediastinal, supramammary, mandibular, and some mesenteric lymph nodes and liver should be collected for examination and culture.

Identification of isolates may be usually carried out by determining cultural and biochemical properties. The polymerase chain reaction (PCR) may also be employed for the detection of the *M. tuberculosis* complex. DNA analysis techniques may prove to be faster and more reliable than biochemical methods for the differentiation of *M. bovis* from other members of the *M. tuberculosis* complex. Genetic fingerprinting allows distinguishing between different strains of *M. bovis* and will enable patterns of origin, transmission and spread of *M. bovis* to be described.

The techniques and media used, their standardisation and the interpretation of results must conform to that specified in the OIE Manual of Standards for Diagnostic Tests and Vaccines. Fourth Edition. 2000. Chapter 2.3.3 (bovine tuberculosis).

2. THE TUBERCULIN SKIN TEST

Tuberculin PPD (Purified Protein Derivatives) that fulfil the standards laid down in paragraph 2.1 shall be used for carrying out official tuberculin skin test following the procedures referred to in paragraph 2.2.
2.1. Standards for tuberculin (bovine and avian)

2.1.1. Definition

Tuberculin purified protein derivative (tuberculin PPD, bovine or avian) is a preparation obtained from the heat-treated products of growth and lysis of Mycobacterium bovis or Mycobacterium avium (as appropriate) capable of revealing a delayed hypersensitivity in an animal sensitised to microorganisms of the same species.

2.1.2. Production

It is obtained from the water-soluble fractions prepared by heating in free-flowing steam and subsequently filtering cultures of M. bovis or M. avium (as appropriate) grown in a liquid synthetic medium. The active fraction of the filtrate consisting mainly of protein is isolated by precipitation, washed and re-dissolved. An antimicrobial preservative that does not give rise to false positive reactions, such as phenol may be added. The final sterile preparation free from mycobacterium is distributed aseptically into sterile tamper-proof glass containers which are then closed so as to prevent contamination. The preparation may be freeze-dried.

2.1.3. Identification the product

Inject a range of graded doses intradermally at different sites into suitably sensitised albino guinea-pigs, each weighing not less than 250 g. After 24 h to 28 h, reactions appear in the form of oedematous swellings with erythema with or without necrosis at the points of injection. The size and severity of the reactions vary according to the dose. Un-sensitised guinea-pigs show no reactions to similar injections.

2.1.4 Test

2.1.4.1. PH: The pH is 6.5 to 7.5

2.1.4.2. Phenol: If the preparation to be examined contains phenol, its concentration is not more than 5 g/l.

2.1.4.3. Sensitising effect: Use a group of three guinea-pigs that have not been treated with any material which will interfere with the test. On 3 occasions at intervals of five days inject intradermally into each guinea-pig a dose of the preparation to be examined equivalent to 500 IU in 0.1 ml. 15 to 21 days after the third injection inject the same dose (500 IU) intradermally into these animals and into a control group of three guinea-pigs of the same mass and which have not previously received injections of tuberculin. 24 to 28 hours after the last injections, the reactions of the two groups are not significantly different.

2.1.4.4. Toxicity: Use two guinea-pigs, each weighing not less than 250 g and which have not previously been treated with any material which will interfere with the test. Inject subcutaneously into each guinea-pig 0.5 ml of the preparation to be examined. Observe the animals for seven days. No abnormal effects occur during the observation period.


2.1.5. Potency

The potency of tuberculin purified protein derivative (bovine and avian) is determined by comparing the reactions produced in sensitised guinea-pigs by the intradermal injection of a series of dilutions of the preparation to be examined with those produced by known concentrations of a reference preparation of tuberculin (bovine or avian, as appropriate) purified protein derivative calibrated in International Units.

To test the potency, sensitise not fewer than nine albino guinea-pigs, each weighing 400 g to 600 g, by the deep intramuscular injection of 0.0001 mg of wet mass of living M. bovis of strain AN5 suspended in 0.5 ml of a 9 g/l solution of sodium chloride R for bovine tuberculin, or a suitable
dose of inactivated or live M. avium for avian tuberculin. Not less than four weeks after the
sensitisation of the guinea-pigs, shave their flanks to provide space for not more than four injection
sites on each side. Prepare dilutions of the preparation to be examined and of the reference
preparation using isotonic phosphate-buffered saline (pH 6.5-7.5) containing 0.005 g/L of
polysorbate 80 R. Use not fewer than three doses of the reference preparation and not fewer than
three doses of the preparation to be examined. Choose the doses such that the lesions produced
have a diameter of not less than 8 mm and not more than 25 mm. Allocate the dilutions randomly
to the sites using a Latin square design. Inject each dose intradermally in a constant volume of 0.1
ml or 0.2 ml. Measure the diameters of the lesions after 24 to 28 hours and calculate the result of
the test using the usual statistical methods and assuming that the diameters of the lesions are
directly proportional to the logarithm of the concentration of the tuberculins.

The test is not valid unless the fiducial limits of error (P = 0.95) are not less than 50% and not
more then 200% of the estimated potency. The estimated potency is not less than 66% and not
more than 150% of the stated potency for bovine tuberculin. The estimated potency is not less than
75% and not more than 133% of the stated potency for avian tuberculin. The stated potency is not
less than 20000 IU/ml for both tuberculins (bovine and avian).

2.1.6. Storage

Store protected from light, at a temperature of 5 t 3 °C.

2.1.7. Labelling

The label states:
- the potency in International Units per millilitre,
- the name and quantity of any added substance,
- for freeze-dried preparations.
    -- the name and volume or the reconstituting liquid to be added,
    -- that the product should be used immediately after reconstitution.

2.2. Test procedures

2.2.1. The following shall be recognised as official intradermal tuberculin tests:
- the single intradermal test: this test requires a single injection of bovine tuberculin,
- the intradermal comparative test: this test requires one injection of bovine tuberculin and one
injection of avian tuberculin given simultaneously.

2.2.2 The dose of tuberculin injected shall be:
- not less than 2 000 IU of bovine tuberculin,
- not less than 2 000 IU of avian tuberculin.

2.2.3 The volume of each injection dose shall not exceed 0.2 ml.

2.2.4 Tuberculin tests shall be carried out by injecting tuberculin(s) into the skin of the neck. The
injection sites shall be situated at the border of the anterior and middle thirds of the neck. When
both avian and bovine tuberculins are injected in the same animal, the site for injection of avian
tuberculins shall be about 10 cm from the crest of the neck and the site for the injection of bovine
tuberculin about 12.5 cm lower on a line roughly parallel with the line of the shoulder or on
different sides of the neck; in young animals in which there is not room to separate the sites
sufficiently on one side of the neck, one injection shall be made on each side of the neck at
identical sites in the centre of the middle third of the neck.

2.2.5 The technique of tuberculin testing and interpretation of reactions shall be as follows:

2.2.5.1 Technique:

Injection sites shall be clipped and cleansed. A fold of skin within each clipped area shall be taken
between the forefinger and thumb and measured with callipers and recorded. The dose of
tuberculin shall then be injected by a method that ensures that the tuberculin is delivered
intradermically. A short sterile needle, bevel edge outwards, with graduated syringe charged with tuberculin, inserted obliquely into the deeper layers of the skin may be used. A correct injection shall be confirmed by palpating a small pea-like swelling at each site of injection. The skin-fold thickness of each injection site shall be remeasured 72 hours (+- 4 hours) after injection and recorded.

2.2.5.2 Interpretation of reactions

The interpretation of reactions shall be based on clinical observations and the recorded increase(s) in skin-fold thickness at the sites of injection 72 hours after injection of tuberculin(s).

(a) Negative reaction: if only limited swelling is observed, with an increase of not more than 2 mm in the thickness of the fold of skin without clinical signs such as diffuse or extensive oedema, exudation, necrosis, pain or inflammation of the lymphatic ducts in that region or of the lymph nodes.

(b) Inconclusive reaction: if no clinical signs such as mentioned in a) are observed and if the increase in skin-fold thickness is more than 2 mm and less than 4 mm.

(c) Positive reaction: if clinical signs such as mentioned in a) are observed or there is an increase of 4 mm or more in the thickness of the fold of skin at the injection site.

2.2.5.3 The interpretation of official intradermal tuberculin tests shall be as follows:

2.2.5.3.1. Single intradermal test:

(a) positive: - a positive bovine reaction as defined in paragraph 2.2.5.2(c);

(b) inconclusive: an inconclusive reaction as defined in paragraph 2.2.5.2(b);

(c) negative: a negative bovine reaction as defined in paragraph 2.2.5.2(a).

Animals inconclusive to the single intradermal test shall be subjected to another test after a minimum of 42 days.

Animals which are not negative to this second test shall be deemed to be positive to the test.

Animals positive to the single intradermal test may be subjected to an intradermal comparative test if false positive reaction or interference reaction is suspected.

2.2.5.3.2. Intradermal comparative test for the establishment and maintenance of officially tuberculosis-free herd status:

(a) positive: - a positive bovine reaction which is more than 4 mm greater than the avian reaction, or the presence of clinical signs:

(b) inconclusive: a positive or inconclusive bovine reaction which is from 1 to 4 mm greater than the avian reaction, and the absence of clinical signs:

(c) negative: a negative bovine reaction, or a positive or inconclusive bovine reaction but which is equal to or less than a positive or inconclusive avian reaction and the absence of clinical signs in both cases.

Animals inconclusive to the intradermal comparative test shall he subjected to another test after a minimum of 42 days Animals, which are not negative to this second test, shall be deemed to be positive to the test.

2.2.5.3.3. Officially tuberculosis-free herd status may be suspended and animals from the herd shall not be allowed to enter intra-Community trade until such time as the status of the following animals is resolved:
(a) animals which have been deemed to be inconclusive to the single intradermal tuberculin test:

(b) animals which have been deemed to be positive to the single intradermal tuberculin test but are awaiting retest with an intradermal comparative test:

(c) animals which have been deemed to be inconclusive to the intradermal comparative test.

2.2.5.3.4. Where animals are required by Community legislation to be subjected to an intradermal test prior to movement, the test shall be interpreted so that no animal which shows an increase in skin-fold thickness greater than 2 mm or the presence of clinical signs is entered into intra-Community trade.

2.2.5.3.5. To enable detection of the maximum number of infected and diseased animals in a herd or in a region, Member States may modify the criteria for the interpretation of the test in order to achieve improved test sensitivity considering all inconclusive reactions referred in 2.2.5.3.1 (b) and 2.2.5.3.2(b) as positive reactions.

3. SUPPLEMENTARY TESTING

To enable detection of the maximum number of infected and diseased animals in a herd or in a region, Member States may authorise the employ of the gamma-interferon assay referred in the OIE Manual of Standards for Diagnostic Tests and Vaccines, 4th Edition, 2000, Chapter 2.3.3. (bovine tuberculosis), in addition to the tuberculin test.

4. STATE INSTITUTES AND NATIONAL REFERENCE LABORATORIES

4.1 Tasks and responsibilities
The State institutes, national reference laboratories or official institutes designated in accordance with Article 6a shall be responsible for the official testing of tuberculins or reagents referred to in paragraphs 2 and 3 respectively in their respective Member States to ensure that each of these tuberculins or reagents is adequate in relation to the standards referred to in point 2.1 and paragraph 3 respectively.
APPENDIX 1(a)


COUNCIL DIRECTIVE of 13 December 1977 establishing the Community criteria for national plans for the accelerated eradication of brucellosis, tuberculosis and enzootic leukosis in cattle (78/52/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,


Having regard to the proposal from the Commission,

Whereas when laying down, in Directive 77/391/EEC, the basic principles for Community intervention for the eradication of brucellosis, tuberculosis and leukosis, the Council decided to establish subsequently the minimum criteria which the national plans for the eradication of the abovementioned diseases should satisfy in order to qualify for a financial contribution by the Community;

Whereas the first of these criteria relates to the acceleration of national plans, so that the campaign undertaken to eradicate the diseases in question in the Member States in which herds are still infected may be carried to a successful conclusion as rapidly as possible; whereas to this end measures should be taken or strengthened, as far as possible simultaneously, concerning, in particular, checks on livestock, the functioning of laboratories and the compensation paid for cattle slaughtered under the eradication plans;

Whereas it is moreover necessary, depending on the diseases in question, to lay down the conditions in which slaughter, isolation, cleaning and disinfection should take place and the use which should be made of certain animal products;

Whereas it is also essential, in order to avoid the risk of reinfection, to practise strict control of movements of cattle, especially between herds of a different health status, and to make those movements conditional on certain tests;

Whereas the date on which Directive 77/391/EEC is to take effect should be fixed,

HAS ADOPTED THIS DIRECTIVE:

Article 1

In order to qualify for the Community financial contribution provided for in Directive 77/391/EEC, each eradication plan referred to in Articles 2, 3 and 4 of that Directive must, in respect of the herds to which it applies, satisfy at least the criteria laid down in the present Directive.

Article 2

For the purposes of this Directive, the following definitions shall apply: 1. in the case of brucellosis in cattle: (a) type B1 bovine herds: herds in whose case the previous clinical history and vaccination and serological status are unknown;

(b) type B2 bovine herds: herds in whose case the previous clinical history and vaccination and serological status are known and in which routine monitoring tests are carried out in accordance with the national rules for bringing these herds up to type B3 or type B4 status;

(c) type B3 bovine herds: brucellosis-free herds within the meaning of Council Directive 64/432/EEC of 26 June 1964 on animal health problems affecting intra-Community trade in bovine animals and swine (2), as last amended by Directive 77/98/EEC (3);

(d) type B4 bovine herds: officially brucellosis-free herds within the meaning of Directive 64/432/EEC;

2. in the case of bovine tuberculosis: (a) type T1 bovine herds: herds in whose case the previous clinical history and the tuberculin-test status are unknown;

(b) type T2 bovine herds: herds in whose case the previous clinical history and the tuberculin-test status are known, and in which routine monitoring tests are carried out in accordance with the national rules for bringing these herds up to type T3 status;
(c) type T3 bovine herds: officially tuberculosis-free herds within the meaning of Directive 64/432/EEC;

3. suspect animal: any bovine animal which shows symptoms indicating the possible presence of tuberculosis, brucellosis or bovine enzootic leucosis and for which an appropriate diagnosis has neither officially confirmed nor officially ruled out the presence of one or more of these diseases;
4. official veterinarian: the veterinarian designated by the competent central authority of the Member State;
5. means of transport: those parts of motor vehicles, rail vehicles and aircraft set aside for loading, the holds of ships and containers for land, sea or air transport.

CHAPTER I General provisions

Article 3

Member States shall ensure that, in all cases, the acceleration provided for in Directive 77/391/EEC involves a significant shortening of the period of time necessary for successfully completing eradication plans as compared with the time taken by programmes currently in progress.

The measures to be taken to achieve this end shall be the following: 1. The proportion of the national cattle population which is the subject of eradication and preventive measures must be so increased that most or all such cattle may be placed or kept under monitoring controls as soon as possible.
2. Compensation for animals slaughtered on the instructions of the official veterinarian must be so adjusted that breeders are appropriately compensated.
3. The number of laboratory staff must be increased and there must be an improvement in the conditions for carrying out diagnoses in the laboratory in so far as such steps still remain to be taken so as to attain a level that is sufficient to make possible the measures defined in point 1.
4. Measures introduced to combat enzootic diseases must be systematically applied.

To guarantee that acceleration is fully effective, the Member States shall ensure that all the measures outlined in points 1 to 4 are applied.

Article 4

1. For the purpose of officially monitoring the movement of the animals, Member States shall ensure that cattle are registered and identified in a permanent manner.
2. Member States shall, for each of the diseases for which an eradication plan exists, draw up and keep up to date an official record of bovine herds covered by such a plan classified according to their health status.

CHAPTER II Specific provisions relating to brucellosis in cattle

CHAPTER III Specific provisions relating to bovine tuberculosis

Article 13

Member States shall ensure that under a plan for the accelerated eradication of tuberculosis: (a) the presence and suspected presence of tuberculosis are compulsorily and immediately notifiable to the competent authority;
(b) the following are prohibited: (i) any therapeutic or desensitizing treatment of tuberculosis;
(ii) anti-tuberculosis vaccination.

Article 14

1. Where a herd contains an animal suspected of having tuberculosis, the competent authorities shall ensure that official investigations are carried out as soon as possible to confirm or rule out the presence of that disease.
Pending the outcome of these investigations, the competent authorities shall order:
- the herd to be placed under official surveillance,
- the prohibition of any movement into or out of the herd unless authorized by the competent authorities for the purpose of slaughter without delay,
- isolation within the herd of the suspect animals.

2. The orders referred to in paragraph 1 shall not be lifted until the presence or suspected presence of tuberculosis in the herd concerned has been officially ruled out.

3. Where the presence of tuberculosis is officially confirmed, the Member States shall take appropriate measures to prevent any spread of the disease and shall ensure in particular that:
- all movement into or out of the herd in question is prohibited unless authorized by the competent authorities for the purpose of slaughter without delay,
- cattle in which the presence of tuberculosis has been officially confirmed, and cattle which may have been infected by them, are isolated within the herd,
- the cattle undergo an examination for tuberculosis without delay,
- cattle in which the presence of tuberculosis has been officially confirmed, cattle which have been examined as stipulated in the third indent with unfavourable results, and cattle considered by the competent authorities as infected are isolated and marked until their slaughter pursuant to Article 15,
- milk from infected cows may only be fed to animals on the same farm after suitable heat treatment,
- without prejudice to national provisions concerning foodstuffs, milk from cows from an infected herd, cannot be delivered to a dairy, except to undergo suitable heat treatment,
- carcasses, half-carcasses, quarters, pieces and offal from infected cattle intended for use as feed for animals are treated in such a way as to avoid contamination,
- official regulations for the control of establishments such as carcase disposal plants ensure that there is no danger of the material produced spreading tuberculosis,
- manure from sheds or other quarters used by the animals is stored in a place inaccessible to farm animals, treated with a suitable disinfectant and stored for at least three weeks. Use of disinfectant is not required if the manure is covered with a layer of uninfected manure or earth. Liquid waste from sheds or other quarters used by the animals must be disinfected if it is not collected at the same time as the manure.

Article 15

Member States shall ensure that, following a bacteriological, pathological or tuberculin examination, animals in which the presence of tuberculosis has been officially established and those considered by the competent authorities to be infected are slaughtered under official supervision as soon as possible and not later than 30 days after the owner or the person in charge has been officially notified of the results of the tests and of his obligation, under the eradication plan, to slaughter the cattle concerned within that time limit.

However, in the case of animals which have been examined for tuberculosis with unfavourable results without showing clinical symptoms of the disease, the competent authorities may extend to not more than three months the period provided for in the above paragraph, - in the case of a female animal which is expected to calve within the three month period,
- where they order the slaughter of all cattle in a herd of more than 20 head in a region in which, for technical reasons connected with the capacity of the slaughter-houses designated for this purpose, slaughter cannot be carried out within the 30 days.

Article 16

Member States shall ensure that:
1. after the slaughter of the cattle referred to in Article 15 and prior to restocking, sheds and other herd quarters, and all containers, equipment and other articles used for the animals are cleaned and disinfected under official supervision, in accordance with the instructions given by the official veterinarian;
2. all means of transport, containers and equipment are cleaned and disinfected after the transport of animals from an infected herd or of materials from such animals or of materials or substances which have been in contact with such animals. Loading areas for such animals must be cleaned and disinfected after use;
3. the disinfectant to be used and its concentrations are officially authorized by the competent authority of the Member State concerned.
Article 17

Member States shall ensure that after the slaughter of the cattle referred to in Article 15, - without prejudice to the provisions of Article 19, no cattle may leave the herd concerned, unless authorization has been given by the competent authority for the purpose of slaughter without delay,

- tuberculosis tests are carried out on the herd concerned to confirm that the disease has been eliminated,

- the herd is not re-stocked until the cattle over six weeks old remaining in it have passed one or more official tuberculosis tests.

Article 18

Member States shall ensure that, under a plan for the eradication of tuberculosis, officially supervised intradermal tuberculin testing is carried out on all cattle over six weeks old at least every six months in type T1 and type T2 herds until such time as they become type T3 herds.

Article 19

Member States shall ensure that: (i) any animal from a type T1 herd and destined for a type T2 herd: - has passed an intradermal tuberculin test carried out within the 30 days prior to movement and is accompanied by a certificate to this effect from the official veterinarian,

- is isolated immediately upon arrival for at least 60 days and has passed a further official intradermal tuberculin test before admission to the herd;

(ii) any animal from a type T2 herd and destined for another type T2 herd: - has passed an intradermal tuberculin test within the 30 days prior to movement and is accompanied by a certificate to this effect from the official veterinarian,

- does not come into contact, during transfer, with cattle from herds of a lower health status;

(iii) all transfers of cattle between type T3 herds are carried out subject to observance of the requirements of Directive 64/432/EEC.

Article 20

Member States shall ensure that:

- official control measures are taken to prevent a herd in which tuberculosis has been eliminated from being re-infected from other sources of infection,

- all movements of cattle into and within herds covered by an eradication plan are subject to official supervision,

- the movement control measures referred to in the second indent can be applied without prejudice to existing Community measures concerning movement into and out of officially tuberculosis-free herds.

CHAPTER IV Specific provisions relating to enzootic bovine leukosis

CHAPTER V Final provisions

Article 28

Before expiry of the three-year period provided for in Directive 77/391/EEC, the Commission shall submit to the Council a report on the application of the plans provided for in that Directive, accompanied if necessary by proposals to achieve closer harmonization of national preventive measures.

Article 29


2. Member States shall bring into force the laws, regulations and administrative provisions necessary for implementation of national plans for accelerated eradication adopted in accordance with Article 9 (2) of Directive 77/391/EEC, on the date laid down by the Commission in its Decision approving the plans, and for plans approved during 1978, not later than 31 December 1978.

3. The three-year period of execution provided for in Article 6 (1) of Directive 77/391/EEC shall run, for each Member State, from the date laid down by the Commission pursuant to paragraph 2. However, Community finance shall in all cases be restricted to slaughterings carried out before 1 January 1982.

4. The Council, acting unanimously on a proposal from the Commission, may, where implementation of the plan on the date laid down would meet with considerable difficulties in some Member States, postpone for such States the dates specified in paragraphs 2 and 3 by not more than one year.
APPENDIX 1(b)

S.I. No. 58 of 2015

ANIMAL HEALTH AND WELFARE (BOVINE TUBERCULOSIS) REGULATIONS 2015

Notice of the making of this Statutory Instrument was published in “Iris Oifigiúil” of 20th February, 2015.

I, SIMON COVENEY, Minister for Agriculture, Food and the Marine, in exercise of the powers conferred on me by sections 32, 34 and 36 of the Animal Health and Welfare Act 2013 (No. 15 of 2013), hereby make the following regulations:

Part 1

Preliminary

Citation and commencement

1. (1) These Regulations may be cited as the Animal Health and Welfare (Bovine Tuberculosis) Regulations 2015.

(2) These Regulations come into operation on 1 April 2015.

Interpretation

2. (1) In these Regulations-

“Act” means the Animal Health and Welfare Act 2013;


“bovine” means a bovine animal (including the species Bison bison and Bubalus bubalus);


“eligible bovine” means a bovine other than a bovine under 6 weeks of age that was born in the herd;
“epidemiological unit” means a number of animals (whether owned by the one person or otherwise) that are held, kept or handled in such a manner that they share the same likelihood of exposure to bovine tuberculosis and the control of the spread of infectious disease from the unit can be facilitated;

“free bovine” means a bovine whose test validity period in accordance with Regulation 5 has not expired, is not subject to any restriction and is in a herd that is not subject to any restriction;

“herdnumber” means the number assigned to a herd under Regulation 3;

“herdowner” means a person who has a beneficial interest in a herd and has registered that interest in accordance with Regulation 3;

“herd test” means a test for tuberculosis conducted, as directed by the Minister;

“holding” means any establishment, construction or, in the case of an open air farm, any place in which bovines are held, kept or handled;

“inconclusive reactor” means a bovine which has given a result referred to in Regulation 12 (1) (c);

“keeper” means a natural person who is registered as the keeper of a herd and who is, irrespective of ownership, responsible for the day to day care and welfare of the herd;

“movement permit” means a permission issued by the Minister under Regulation 28;

“passport” means a record issued by the Minister in accordance with Article 6.1 of Regulation (EC) No 1760/2000 of the European Parliament and of the Council of 17 July 2000 and includes a cattle identity card referred to in Regulation 32;

“reactor” means a bovine which the Minister, by reason of a test or otherwise, has reasonable grounds to suspect is tuberculosis infected or is capable of spreading tuberculosis;

“reactor tag” means an eartag issued by the Minister for the purpose of attaching to a bovine that has, in the opinion of a veterinary practitioner, reacted positively to a test under Regulation 6(a) or which in the opinion of an authorised officer is a reactor;

“Regional Veterinary Office” means an office of the Minister with responsibility for administering disease controls in a particular area;

“restricted herd or holding” means a herd or holding restricted under Regulation 4, 10, 13, 17, 18 or 20;

“test” means a test of a bovine for tuberculosis as set out in Regulation 6 and related activities;

“veterinary practitioner” means a person registered under Part 4 of the Veterinary Practice Act 2005 (No. 22 of 2005).

(2) A word or expression which is used in these Regulations and is also used in Council Directive 64/432/EEC in so far as the Directive relates to bovines, has, unless the context otherwise requires, the same meaning in these Regulations, as it has in that Directive.

Part 2

Registration of a Herd

Herdnumber

3. (1) A person shall not own or keep a bovine, unless the bovine—

(a) is part of a bovine herd that has been registered with the Minister and the Minister has assigned a herdnumber to that herd, and

(b) is identified in accordance with the animal identification regulations.

(2)(a) Subject to subparagraph (b), a person shall not keep an animal susceptible to tuberculosis on a holding that is used primarily for farming purposes unless all such animals on the holding are contained in the same epidemiological unit and have the one herdnumber.

(b) An animal susceptible to tuberculosis in subparagraph (a) does not include porcine animals.

(3)(a) A person who intends to establish a new herd shall apply to the Minister for registration of the herd and herdnumber and supply such information as the Minister may reasonably require, including nominating a keeper for the herd.

(b) The Minister may refuse an application for registration of a herd where—

(i) a person is disqualified under section 58 of the Act,

(ii) the Minister is of the view that the person is unsuitable to be a herdowner or keeper due to age, infirmity or ability to ensure the health or welfare of the animal, or

(iii) the Minister is of the view that the herd does not constitute a separate epidemiological
unit.

(4)(a) A person who has a beneficial interest in a herd but who is not the keeper may register an interest in the herd in the manner set out by the Minister and shall provide documentary evidence to support the registration of interest when requested.

(b) The Minister may refuse to register an interest under subparagraph (a).

(5) The Minister may register and assign a herd number to a herd which forms an "epidemiological unit and attach such conditions as the Minister considers appropriate.

(6) The Minister may alter, vary or cancel a condition of registration or cancel the registration or assignment of keeper or herdowner.

(7) Where it appears to the Minister that the identity of the herdowner or keeper cannot reasonably be ascertained or the herdowner or keeper is not suitable, the Minister may nominate a natural person to act as keeper of that bovine and the person so nominated shall fulfil the function of a keeper.

(8) A herdowner, who is not the keeper, shall be considered responsible with the keeper for the herd and the holding for the purposes of these Regulations.

(9) Where the Minister proposes to exercise any of the powers conferred on him or her under paragraph 3(b), 4(b) or 6, he or she shall—

(a) notify the applicant in writing of the proposal and of the reasons for the proposal, and that he or she may make representations to the Minister in relation to the proposal within twenty one days of the notification,

(b) consider a representation duly made before deciding whether to proceed with, modify or annul the proposal, and

(c) notify the applicant of the decision and the reasons for the decision.

Part 3
Testing of Bovines for Bovine Tuberculosis

Requirement to test and costs

4. (1) A keeper or herdowner shall present all bovines on the holding for inspection, examination and testing for tuberculosis as directed by the Minister and all the eligible bovines kept on the same holding shall be tested as a single herd.

(2) The keeper or herdowner shall be liable for all costs related to testing, unless otherwise determined by the Minister.

(3) Notwithstanding paragraph (1), the Minister may—

(a) require or,

(b) otherwise authorise,
a keeper or herdowner to have all bovines or a particular bovine in a herd tested within a period and in a manner directed by the Minister.

(4) If a keeper or herdowner fails to comply with the test requirement under this Regulation, the Minister may—

(a) declare the holding to be a restricted holding,

(b) test or arrange to have tested a bovine in the herd at the cost to the keeper or herdowner.

Validity of test

5. The result of a test which is interpreted by the Minister, in accordance with Regulation 12 (1), as negative shall be valid for a period not exceeding twelve months from the date on which the test is conducted or for such shorter period as may be determined by the Minister.

Test for tuberculosis

6. The following are tests for the presence of tuberculosis—

(a) in the case of a live bovine—

(i) the single intradermal comparative tuberculin test,

(ii) the Interferon-Gamma Assay, or

(iii) any other test approved by the Minister, and

(b) in the case of a dead bovine, suspect lesion of tuberculosis or other tissue taken post mortem—

(i) histopathology,

(ii) culture, or

(iii) any other test approved by the Minister,

performed in a laboratory nominated by the Minister for this purpose.
Permission to test

7. (1) A person shall not conduct a test on a bovine for tuberculosis unless he or she has been authorised under section 37(1) of the Act for the purposes of section 38(1) of the Act in relation to the testing for bovine tuberculosis in ruminants.

(2) A person authorised under section 37(1) of the Act for the purposes of section 38(1) in relation to the testing for bovine tuberculosis in ruminants shall conduct a test in accordance with these Regulations and any terms and conditions determined by the Minister.

Conduct of test in live bovines

8. (1) Subject to Regulation 4(1), a keeper or herdowner may, with the permission of the Minister, complete a test in parts and, where the test is completed in parts, the keeper shall have all parts completed within fourteen days of commencement of the first part of the test.

(2) The keeper or herdowner shall—

(a) provide assistance as required to enable inspection, examination and testing to be conducted,

(b) assemble, pen, restrain or otherwise secure a bovine, in a manner that facilitates the inspection, examination and testing,

(c) if requested, make a declaration in writing in the form determined by the Minister setting out the number and location of the bovines on the holding and confirming that all bovines have been presented,

(d) prior to the commencement of a test, inform the person conducting the inspection, examination and test of any circumstances, including the previous use or application of any substance, which may affect the accuracy of the test on a bovine in the herd,

(e) prior to the commencement of a test, inform the person conducting the inspection, examination and test of any substance administered to the animal in the previous seven days or any substance administered, for which the date of withdrawal has not expired, and

(f) surrender the passport of each bovine on the holding to the person conducting the test.

(3) Without prejudice to section 10(2) of the Act, from the time a keeper or herdowner is notified by the Minister to undertake a test and until the test is completed, he or she shall not—

(a) administer or cause or permit to be administered to a bovine subject to a test any prophylactic or therapeutic treatment for which a withdrawal period is applicable, other than water or non-medicated feedingstuffs taken orally by a bovine in the normal course of animal husbandry, unless—

(i) such withdrawal period shall have expired before the test commences, or

(ii) the prescribing person has certified that the treatment is urgent and the person conducting the test has given written permission to do so,

or

(b) carry out any process or operation on a bovine that may interfere with a test or the interpretation of a test.

(4) From the commencement of a test until the results have been determined in accordance with these Regulations, a person shall—

(a) not move a bovine from the holding other than in accordance with a movement permit, and

(b) keep the bovine at the same location on the holding.

(5) Where a person discovers that a bovine present on the holding and required to be presented for testing was not presented or that a bovine injected with tuberculin at the commencement of the test was not subsequently presented for reading, that person shall immediately notify the Minister.

(6) A person shall not interfere with any evidence of tuberculosis or any test.

(7) A person shall not have in his or her possession without lawful reason—

(a) a bovine whose test has been interfered with, or

(b) material infected with tuberculosis.

(8) A person—

(a) who receives a passport under paragraph (2) shall forward, where directed by the Minister, that passport to the Regional Veterinary Office, and

(b) who conducts a test, at which the test is conducted in parts, shall record and report in writing in a manner determined by the Minister, including by electronic means, the location where each part of the test was conducted.

Identification of bovines to be tested

9. (1) If a bovine being tested or inspected is not identified in accordance with the animal
identification regulations—

(a) the person conducting the test shall, at the commencement of the test or inspection, attach a tag approved and supplied by the Minister for temporary identification purposes to the left ear of the bovine concerned, and

(b) a person shall not interfere with the tag attached for temporary identification purposes until the test is complete and the bovine is correctly identified and the temporary tag has been correlated with the correct identification in a manner set out by the Minister.

(2) The keeper or herdowner of a bovine identified under paragraph (1) shall arrange to fulfil the requirements of the animal identification regulations without delay.

(3) A person shall not move a bovine identified under paragraph (1) off a holding—

(a) other than in accordance with the directions of the Minister, or

(b) until the requirement of the animal identification regulations are fulfilled.

Reading of test

10. (1) If, in the opinion of the person who carried out the test, no bovine tested has given a positive or inconclusive reactor result to that test, that person shall report the result of the test within 7 working days of the completion of the test in the manner directed by the Minister.

(2) If, in the opinion of the person who carried out the test, a bovine has given a positive result, that person shall—

(a) apply a reactor tag to that bovine,

(b) inform the keeper or herdowner—

(i) that a bovine has given a positive reaction to the test, and

(ii) that, pending the interpretation of the test under Regulation 12, the tuberculosis free status of the holding is suspended and the holding is a restricted holding, and

(iii) of the provisions applicable to a restricted holding, a reactor animal, an inconclusive reactor,

and

(c) within three working days of the completion of the test, report the result of the test in the manner directed by the Minister.

(3) If, in the opinion of the person who carried out the test, a bovine has given an inconclusive reactor result and no other bovine on the holding has given a positive result, that person shall—

(a) inform the keeper or herdowner that a bovine has given an inconclusive reactor result to the test and advise the keeper or herdowner, pending the determination of the test under Regulation 12—

(i) that the tuberculosis free status of the holding is suspended and the holding is a restricted holding, and

(ii) of the provisions applicable to a restricted holding and inconclusive reactor which apply, and

(b) within 3 working days of the completion of the test, report the result of the test in the manner directed by the Minister.

(4) If a person who carried out the test forms the opinion that the reaction observed and purported to be as a result of the test is not the normal intradermal reaction to such a test, he or she shall immediately report his or her opinion to the Minister.

(5) The date of the test as certified by the person who carried out the test and held on the Minister’s electronic records is the legal date of test.

(6) A person shall not interfere with a reactor tag without lawful reason.

(7) A herdowner, keeper or any other person concerned with a bovine that is subject to the provisions of paragraph (2) or (3) shall comply with the applicable provisions mentioned in paragraph (2)(b)(iii) or 3(a)(ii) as the case may be.

Record of tests

11. A person who carries out a test shall retain his or her records of a test or sampling for not less than 6 years and these records shall be made available to the Minister on request.

Part 4

Results of Bovine Tuberculosis Tests

Interpretation of test

12. (1) The Minister may interpret the result of a test as—

(a) positive,
(b) negative,
(c) inconclusive, or
(d) not determined.

(2) Where the Minister interprets a test result as positive, he or she shall determine the bovine a reactor.

(3) Where the Minister interprets a test result as inconclusive or not determined, he or she may declare the bovine a reactor.

(4) Notwithstanding the result of a test, the Minister may, where he or she has reasonable grounds to suspect that a bovine is infected with bovine tuberculosis or is capable of spreading tuberculosis, declare the bovine a reactor.

**Action on foot of determination of test result**

13. (1) Where the Minister determines that a bovine is a reactor, he or she shall—
   (a) declare the holding to be a restricted holding, and
   (b) notify the herdowner or keeper as soon as practicable that the holding is restricted and the conditions applicable to,
      (i) the restricted holding, and
      (ii) the reactor.

(2) Where the Minister interprets that a bovine has given an inconclusive reactor result, he or she may—
   (a) declare the holding to be a restricted holding, and
   (b) notify the herdowner or keeper as soon as practicable that the holding is restricted and the conditions applicable to,
      (i) the restricted holding, and
      (ii) the reactor or bovine giving an inconclusive reactor test result.

(3) Where the Minister declares a test result as not determined, he or she shall restrict the herd and subject the bovine and herd to additional tests, including tests to be conducted post-mortem, as appropriate, to determine the status of the bovine.

(4) Where the Minister forms an opinion, at the time of interpretation or subsequently, that the reaction observed and purported to be as a result of a test under Regulation 6(a) is not a normal intradermal response to tuberculin PPD (Purified Protein Derivatives), he or she may—
   (a) declare the test on that bovine to be null and void or declare that the bovine is a reactor,
   (b) restrict the holding,
   (c) subject the herd or bovines within the herd to test under Regulation 6(a) at an interval of not less than 42 days from the previous injection of tuberculin or substance,
   (d) seize the bovine,
   (e) slaughter or destroy the bovine, or cause it to be so slaughtered or destroyed without compensation to the herdowner, or
   (f) seize other material considered to be of an evidential nature.

(5) A keeper or herdowner shall, immediately on notification that a bovine is a reactor, isolate the reactor from the remainder of the herd and from any animal of a species susceptible to tuberculosis until—
   (a) the reactor has been removed from the herd in accordance with the conditions set down by the Minister,
   (b) the reactor has otherwise been determined by the Minister not to be a reactor, or
   (c) the tuberculosis free status of the herd is restored and the herd is derestricted by the Minister.

(6) Subject to paragraph (1), (2) and (3), a keeper or herdowner shall, on notification that a bovine has given an inconclusive reactor result, isolate that bovine from the remainder of the herd and from any animal of a species susceptible to tuberculosis until—
   (a) that bovine has reacted negatively to a test,
   (b) that bovine has been removed from the herd in accordance with conditions set down by the Minister,
   (c) that bovine has been determined by the Minister not to be an inconclusive reactor, or
   (d) the tuberculosis free status of the herd is restored and the herd is derestricted by the Minister.

(7) The Minister may require that a bovine referred to in paragraph (6) be re-tested and, notwithstanding that if it gives a negative result, it may not be moved from the herd in which it was last tested and in which it gave an inconclusive reactor result, other than direct to slaughter, except with the permission of the Minister.
Retesting

14. (1) A person shall not test, or cause or permit a reactor to be tested with tuberculin unless such a test is authorised by the Minister.

(2) A person shall not, without the approval of the Minister, cause or permit a bovine to be tested with tuberculin within 42 days of a previous injection of tuberculin beginning on the day on which the test was commenced unless the bovine is part of a herd the subject of a herd test.

Part 5
Prevention of Spread of Bovine Tuberculosis

Prevention of spread of tuberculosis

15. (1) A veterinary practitioner, on suspecting the presence or finding evidence of tuberculosis in a bovine or a species susceptible to tuberculosis, shall—
   (a) immediately and in any event before the expiry of the same working day inform the Regional Veterinary Office in the area in which the holding is located, and
   (b) inform the keeper or person in charge of the bovine or in the case of an animal susceptible to tuberculosis any person whom the veterinary practitioner believes to be the keeper, person in charge or owner of the land on which the animal is present and advise such person of the provisions applicable to a restricted holding.

(2) A veterinary practitioner on suspecting the presence or finding evidence of tuberculosis in a carcass shall—
   (a) immediately inform the Regional Veterinary Office in the area in which the carcass is located and take representative samples from the carcass including the evidence found of tuberculosis, and
   (b) submit the samples to a laboratory nominated by the Minister in accordance with the directions of the Minister.

(3) A person, other than a veterinary practitioner, who has grounds to believe that tuberculosis is present or upon finding evidence of tuberculosis in—
   (a) a bovine, or
   (b) a species susceptible to tuberculosis, or
   (c) any carcass
shall, as soon as possible and in any case before the end of the next working day, inform the Regional Veterinary Office in the area that the bovine, susceptible animal or carcass is situated.

Action of keeper or herdowner to prevent spread of tuberculosis

16. Where there is a reactor or the presence of tuberculosis is suspected in an animal of a species susceptible to tuberculosis, the keeper, person in charge or owner of the animal shall—
   (a) take all reasonable steps to prevent the infection of animals susceptible to bovine tuberculosis, including preventing the reactor or an animal suspected of being infected with tuberculosis from being in contact with other susceptible animals, and
   (b) ensure that, from the time the reactor is identified or the presence of tuberculosis is suspected, no bovine is moved or permitted to be moved on to or off the holding except in accordance with conditions set down by the Minister.

Post mortem and laboratory results

17. (1) Where suspect tuberculosis lesions are found post-mortem in a bovine, the Minister shall restrict the herd from which the bovine was delivered or any other herd that the Minister considers at risk of having been exposed to infection.

(2) Where tuberculosis is diagnosed following laboratory examination of a sample from a bovine, the Minister shall restrict the herd where the bovine was kept or any other herd that the Minister considers at risk of having been exposed to infection.

Tracing of suspect or infected bovines

18. (1) Where an authorised officer has reasonable grounds to believe a bovine has been exposed to tuberculosis, the Minister may require the herdowner or keeper of a herd in which the bovine is or has been held to test each bovine in the herd or to have such bovines in the herd tested as the Minister considers reasonable.

(2) If an authorised officer has reasonable grounds to believe that—
(a) tuberculosis is present on a holding,
(b) there is an epidemiological risk that tuberculosis is present, or
(c) there has been a failure to comply with the Act or these Regulations,

he or she may declare the holding to be a restricted holding by serving, or causing to be served, on the herdowner or keeper a notice to that effect and the herd shall remain restricted until the removal of the restriction under Regulation 27.

(3) If—

(a) a holding is declared to be a restricted holding, or
(b) an authorised officer has reasonable grounds to believe that tuberculosis is present on an adjoining holding,

an authorised officer may, in a manner considered appropriate by the authorised officer, cause the existence of tuberculosis to be brought to the notice of the occupiers of an adjoining holding that the authorised officer considers appropriate.

Part 6
Consequences of Restriction

Removal of reactors

19. (1) The herdowner or keeper of a reactor shall facilitate the removal of a reactor to slaughter within 30 days, following the determination by the Minister under Regulation 12(2).
(2) The herdowner or keeper of a reactor shall facilitate the removal to slaughter of such other animals as the Minister may direct within a period as determined by the Minister.
(3) A person shall not move a reactor other than in accordance with a movement permit issued by the Minister.
(4) The herdowner or keeper shall move the reactor in accordance with the terms of that permit within seven days of the date of issue of the permit.
(5) If a herdowner or keeper fails to comply with this Regulation, the Minister may, by notice, require the reactor to be disposed of in the manner set out in the notice within a period which shall not be less than three days and, if the herdowner or keeper fails to comply with the notice, the Minister may seize and dispose of the reactor and the herdowner or keeper shall be liable for any costs incurred by the Minister.

Transportation of reactors

20. (1) A person shall not transport a bovine which is not a reactor with a reactor except with the approval of the Minister.
(2) Subject to paragraph (1), a person shall not transport a reactor with another bovine unless both bovines are from the same holding and are going directly to the same premises for slaughter.
(3) A person shall not, in the course of transport, unload a reactor or a bovine being transported with the reactor, save in an emergency and any premises used for such emergency shall immediately become a restricted holding.
(4) The person in charge of a vehicle used to transport a reactor shall—

(a) clean and disinfect the vehicle and any machinery or equipment used in connection with the reactor immediately following the delivery of the reactor in accordance with the directions of the Minister, and
(b) not use a vehicle to transport a bovine or other animal susceptible to bovine tuberculosis, hay, straw, fodder, or other feedingstuffs until the vehicle has been cleaned and disinfected in accordance with subparagraph (a).

Slaughter of bovines

21. (1) A person shall—

(a) not slaughter or present for slaughter a reactor other than at a premises approved by the Minister for the slaughter of reactors,
(b) not slaughter or present for slaughter a reactor except in accordance with a movement permit,
(c) when presenting a reactor for slaughter, inform the owner or person in charge of a premises approved that the animal is a reactor and present the relevant movement permit.
(2) The Minister may impose such conditions and requirements as he or she considers appropriate in
relation to an approval to slaughter bovines.

(3) A person who breaches an approval or a condition of approval commits an offence.

Compensation

22. (1) Subject to paragraph (2), the Minister may pay, following a direction under section 30 of the Act for the purposes of bovine tuberculosis, an amount not exceeding —
   (a) €3,000 in respect of a bovine, and
   (b) €4,000 in respect of one stock bull or €5,000 in respect of one pedigree stock bull,
on foot of a declaration made under Regulation 13(1) (a) or (2)(a).

(2) The compensation payable in accordance with paragraph (1) shall be subject to the provisions set out in sections 30 to 35 of the Act.

(3) Compensation is not payable in respect of a bovine product, feed or other thing that is destroyed on foot of a declaration made under Regulation 13(1) (a) or (2)(a).

(4) In this Regulation “stock bull” means an adult bull that is kept for breeding within an epidemiological unit on the holding that is subject to a declaration made under Regulation 13(1)(a) or (2)(a).

Valuers and arbitrators

23. (1) The Minister may appoint, for a specified period, one or more persons to act as a valuer (which may be in the form of a panel of valuers) for the purposes of section 32 of the Act.

(2) The Minister may appoint, for a specified period, one or more persons to act as an arbitrator (which may be in the form of a panel of arbitrators) for the purposes of section 33 of the Act.

(3) In making an appointment under paragraph (1) or (2), the Minister will have regard to any agreements entered into from time to time with bodies representative of farmer interests.

Control of product from restricted holding or holding where tuberculosis is suspected

24. (1) A person shall not deliver milk produced by a reactor or a bovine giving an inconclusive reactor result to a test for onward sale or processing.

(2) A person shall not feed milk produced by a reactor or an inconclusive reactor to an animal of a species susceptible to tuberculosis.

(3) The herdowner or keeper shall ensure the safe and lawful disposal of milk from a reactor or a bovine that has given an inconclusive reactor test result.

(4) A person shall not use milk from a bovine on a restricted holding for direct consumption or for manufacturing unless the milk has been subjected to the appropriate heat treatment at an establishment approved by the Minister.

(5) The herdowner or keeper shall—
   (a) immediately following notification that the holding is restricted, inform any person to whom milk has been sold or supplied from the restricted holding,
   (b) on request of the Minister, furnish the name and address of any person who received milk from a restricted holding.

(6) A person shall not sell or supply milk from a restricted holding other than in accordance with directions of the Minister.

(7) A person shall not sell, supply or use an animal product from a reactor or a bovine that has given an inconclusive reactor result other than in accordance with directions of the Minister.

(8) The Minister may inform third parties of the presence of tuberculosis on a holding if the Minister is of the view that it is necessary for the protection of human health, animal health or the environment.

Identification of possible sources of tuberculosis infection

25. (1) A person shall furnish to the Minister, within a period laid down by the Minister, such information as is required by the Minister relating to any holding, establishment, premises or land as is within the person’s power or procurement in regard to—
   (a) whether or not the holding, establishment, premises or land is—
      (i) used, either partly or wholly, for or in connection with bovines, or
      (ii) frequented by bovines,
   (b) the name and address of any person who is or was (during any period determined by the Minister) in occupation of the holding, establishment, premises or land, and
   (c) whether or not the holding, establishment, premises or land is or was (during any period determined by the Minister) let, leased or otherwise used and the name and address of the person to whom, and the period of time for which it is or was let, leased or otherwise used.
(2) A person shall furnish to the Minister such information relating to the movement of or contact with animals susceptible to tuberculosis, as is required by the Minister, within the period laid down by the Minister.

Disinfection

26. A person shall disinfect his or her holding or premises, equipment, vehicle, utensil or other thing used in connection with a bovine in accordance with the directions of the Minister.

Removal of restriction

27. The Minister may remove a restriction which has been imposed under these Regulations when he or she is satisfied that—
(a) all measures prescribed under these Regulations have been complied with,
(b) the herd is a tuberculosis-free bovine herd within the meaning of Council Directive 64/432/EEC and,
(c) the herd no longer constitutes a risk of spreading bovine tuberculosis.

Part 7

Movement and Inspection Generally

Movement

28. (1) The Minister may issue a movement permit in respect of a bovine electronically or otherwise and may attach such conditions as the Minister considers necessary to prevent the spread of tuberculosis.

(2) A person shall not move a bovine other than a free bovine into any holding except in accordance with a movement permit.

(3) A person shall not move a bovine into a restricted holding except in accordance with a movement permit.

(4) A person shall not move a bovine over six weeks of age into a holding or other land, unless—
(a) during the twelve months immediately preceding the date of movement, the bovine has given a negative result to a test, or
(b) the bovine is moved in accordance with a movement permit.

(5) A person shall not move a bovine over six weeks of age out of a holding or other land, unless—
(a) during the twelve months immediately preceding the date of movement the bovine has given a negative result to a test, or
(b) the bovine is moved in accordance with a movement permit.

(6) Notwithstanding paragraph (5), if a bovine over six weeks of age—
(a) that has not been tested in the preceding 12 months, and
(b) comes from a herd which has not been tested in the preceding 12 months
moves from a holding, the Minister shall issue a notice with immediate effect prohibiting the movement of any bovine on or off the holding except in accordance with a movement permit.

(7) Notwithstanding paragraph (5), if a bovine over six weeks of age is moved from a herd that has been tested in the preceding 12 months and—
(a) it has not been tested—
(i) in the preceding 12 months but has been tested in the preceding 18 months, or
(ii) since birth and is over 14 months of age,
the Minister may issue a notice, with immediate effect, prohibiting the movement of any bovine into or out of the holding except in accordance with a movement permit, or
(b) the bovine has not been tested in more than 18 months the Minister shall issue a notice with immediate effect restricting the movement of a bovine into or out of the holding except in accordance with a movement permit.

(8)(a) A notice issued under paragraph (6) shall be addressed to the owner or person in charge of the bovine and remains in force until—
(i) all eligible bovines on the holding give a negative result to a test, or
(ii) the notice is varied by the Minister.

(b) A notice issued under paragraph (7) shall be addressed to the owner or person in charge of the bovine and remain in force until—
(i) all eligible bovines on the holding give a negative result to a test,
(ii) the bovines required by the Minister to be tested give a negative result to the test, or
(iii) the notice is varied by the Minister.

Inspection of bovines

29. (1) An authorised officer may examine a bovine—
(a) on a holding, at an establishment, premises or other land,
(b) which is being moved into or out of a holding, establishment, premises or other land, or
(c) at public sale or show, and may make enquiries in relation to the bovine or perform examinations, sampling, tests or other things as may be reasonably necessary for the administration of these Regulations.

(2) An authorised officer may require a keeper, herdowner or person in charge to collect, pen, restrain or otherwise secure the bovines referred to in paragraph (1) in a manner that will enable the authorised officer to perform an examination, sampling, test or other thing and the keeper, herdowner or person in charge shall provide assistance as required.

Part 8
Passports

Interference with passports
30. (1) A person shall not—
   (a) alter, deface, obliterate or make a false entry on a passport,
   (b) be in possession of or furnish a passport which is altered, defaced, obliterated or contains false or misleading information purporting that a test had been carried out on a particular date, or
   (c) furnish a passport bearing a false entry.

(2) An authorised officer may require a keeper, herdowner or person in charge to collect, pen, restrain or otherwise secure the bovines referred to in paragraph (1) in a manner that will enable the authorised officer to perform an examination, sampling, test or other thing and the keeper, herdowner or person in charge shall provide assistance as required.

Part 9
Penalties

Penal provisions
31. Regulations 3, 4, 7, 8 (1), 8(2), 8(3)(b), 8(4), 8(5), 8(6), 8(7), 8(8), 9, 10, 11, 13, 14, 15, 16, 19, 20, 21, 24, 25, 26, 28, 29 and 30 are penal provisions to which paragraph (b) of section 36(4) of the Act applies.

Part 10
Revocations and savers

Revocations and savers
32. (1) The following Orders are revoked—
   (a) the Bovine Tuberculosis (Attestation of the State and General Provisions) Order 1989 (S.I. No. 308 of 1989),
   (b) the Bovine Tuberculosis (Attestation of the State and General Provisions) (Amendment) Order 1996 (S.I. No. 85 of 1996),
   (c) the Bovine Tuberculosis (Attestation of the State and General Provisions) (Amendment) Order 2000 (S.I. No. 161 of 2000),
   (d) the Bovine Tuberculosis (Attestation of the State and General Provisions) (Amendment) Order 2003 (S.I. No. 32 of 2003),
   (e) the Bovine Tuberculosis (Attestation of the State and General Provisions) (Amendment) Order 2005 (S.I. No. 7 of 2005),
   (f) the Bovine Tuberculosis (Attestation of the State and General Provisions) (Amendment) Order 2010 (S.I. No. 307 of 2010), and
   (g) the Bovine Tuberculosis (Attestation of the State and General Provisions) (Amendment) Order 2012 (S.I. No. 555 of 2012).

(2) A notice, permit or declaration under an instrument revoked by paragraph (1) that is in force immediately before the making of these Regulations continues in force and may be dealt with as if issued under these Regulations.

(3) Where a test has been notified to the keeper as due prior to the making of these Regulations, it shall be taken as if notified under these Regulations.

(4) A cattle identity card issued under an instrument revoked by paragraph (1) shall for the purposes of these Regulations be considered to be a passport as defined in Regulation 2(1).

(5) A reference to an instrument revoked under paragraph (1) shall be construed as a reference to the equivalent provision in these Regulations.

Given under my Official Seal,
17 February 2015.
SIMON COVENEY, Minister for Agriculture, Food and the Marine.

EXPLANATORY NOTE
(This note is not part of the Instrument and does not purport to be a legal interpretation.)
These Regulations replace in codified form a series of Regulations in relation to Bovine Tuberculosis made under the Diseases of Animals Act 1966 which has been replaced by the Animal Health and Welfare Act 2013. The primary purpose of the Regulations is to underpin delivery of the national Bovine Tuberculosis Eradication Programme and to reflect relevant provisions of EU legislation, in particular, Council Directive 64/432/EEC.
APPENDIX 2.1

PVP Quality Control

1 Terms and Conditions attaching to Tuberculin testing and Brucellosis Sampling

1.1 Terms and Conditions applicable to Private Veterinary Practitioners (PVPs) for Eligibility to Test/Sample

[Note: For the purposes of these conditions/instructions “PVP” includes Wholetime Temporary Veterinary Inspectors]

To conduct the single intradermal comparative tuberculin test (SICTT) and sampling for Brucellosis under the Animal Health and Welfare Act 2013, Regulations made thereunder and related EU legislation, PVPs are required to:

A be entered in the current Register of Practitioners for Ireland,
B be authorised by the Minister under the Act, and,
C be approved under the TB Regulations and/or Brucellosis Regulations (Statutory Instruments considered to be Animal Health and Welfare Regulations) as appropriate.
D. commit formally and adhere strictly to the instructions, terms and conditions as laid down in this ER4 document; (Re-approval to test takes place on an annual basis following acknowledgement/acceptance of the ER4 instructions either online or on receipt of the acknowledgement (Form ER4A) attached to the letter that accompanies the ER4 (off-line PVPs only)). Approval/re-approval for testing is conditional on acknowledgment/acceptance of the ER4 instructions. Failure to acknowledge/accept ER4 terms and conditions will result in no approval or re-approval as the case may be.
E. use and update the unique identity codes (user code and password) and access number (Personal Identification number (PIN)) issued for personal use in respect of the Animal Health Computer System (AHCS) (where operating on-line) and keep details of these confidential. A PVP must not allow any third party access to their identity codes and/or PIN as this would facilitate false certification of a test.

In addition to the above new applicants must:

i. apply to the RVO for approval to test by submitting form ER3. The RVO will then arrange a meeting with the SVI at which time the ER67 Contract will be signed by both the SVI and the new PVP;
ii. attend a TB training course as prescribed by the Minister;

No liability shall attach to the Minister for Agriculture, Food and the Marine for compensation or damages or costs in respect of any claims arising from the performance of testing/sampling under the Programmes.

Failure to comply with the instructions, terms and conditions, including those relating to equipment, performance of test, record keeping and other administrative procedures, may, depending on the nature of the infringement, result in sanction appropriate to the infringement up to and including the immediate withdrawal of approval to conduct the Single Intradermal Comparative Tuberculin Test (SICTT) and Blood sampling.

The approval to test/sample may be terminated by notice of either party or following a decision in the context of the Appeals Procedure referred to at (a) below and subject to (b) below:

(a) Disputes arising and regarding the performance of testing by an approved veterinary practitioner (including withdrawal of authorisation to carry out tuberculin testing and or blood sampling) shall be subject to the internal appeals procedures established by the Department.

(b) Notwithstanding the above, the decision of the Minister in relation to all aspects of approval and termination thereof shall be final.
Appendix 2.2 To check handheld re untested animals.

Quport MAHCS Handheld Manual - Page 32

3.5 Viewing Filtered Lists of Animals

MAHCS provides the facility to see a list of animals selected according to a particular filter. By pressing the ‘All…’ button while in Search Mode (make sure keyboard is turned off so you can see the button), you will see a screen like the following:

List Filter

The type of list displayed is selected at the top. Tap on each option to change the list of animals displayed. The list options are:

- Completed – Shows the animals completed for the current day.
- Incomplete – Shows animals not complete for the current day.
- Seen So Far – Shows all the animals found and edited so far. (This is really only of use in BRU-only tests where this test will show all animals that have been seen – even those that were not blood tested)
- Ignored – Lists all ignored animals
- All – Lists all animals (except ignored animals) regardless of what their test status is
- + – Shows all reactor animals
- 0 – Shows all Inconclusive animals

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On the Tag screen Press the F4 button to give the following drop down menu. You can use the arrow keys or type T to give the running Totals of the state of play of the test or R to give untested both for Days 1 & 2.

** F4 Menu **

| group include | G | group include or exclude | e.g. to mark animals for say export certificates or check cards |
| print | P | There are a number of print options. Plain paper/ certs etc |
| wipe | W | wipes TB and blood bottle readings e.g. for re-test situation. |
| report | R | full details of Testing position which is very useful to ensure no readings are missing and other details available from other options displayed e.g. not in group may be used to show card missing. |
| total | T | running totals & batches** (7secs.) quick total & batch count of bloods & TB readings. |
Appendix 2.3 Relevant Circulars

Circular Ref: ER 6A/2000

To the Veterinary Practice/Practitioner named in the address 6 March 2000

Dear Sir/Madam

**Bovine Animal identification and associated matters**

The following points cover areas where you have a direct involvement with bovine identification and also areas where you interact with your clients in this and other regards. A number of problems have arisen over the past year which have drawn attention to this area. As you are aware correct bovine identification is very important from the farmers perspective ensuring eligibility for various EU premia. It is also essential for disease control purposes and for maintenance of live cattle exports and beef markets. It is to be expected that various EU mission visits will concentrate more and more over the coming years on identification issues and our compliance with EU regulations in that regard. Your assistance in ensuring that the integrity of bovine identification is secure, in so far as you can, would be most appreciated.

**Correct animal identification and use of brass tags:**

For reasons of traceability and to promote consumer confidence in the wake of the BSE crisis, EU Regulations now require that all bovine animals born since 1.1.1996 are identified by means of two official plastic tags, inserted one in each ear. Up to the end of 1999 calves had to be identified by the keeper within 30 days of birth and registered within 7 days of identification. This interval was shortened to 20 days from 1.1.2000. Tags which become illegible or are lost require replacement by the keeper as soon as is practicable.

When notifying herdowners of your intention to carry out a test it is imperative, therefore, that you remind them that all animals 20 days of age and over must be identified **before the test commences**.

It is mandatory that the herdowner present all animals in the herd at the time of a herd test. However, home-bred animals under 6 weeks of age do not require testing for results to be valid. All animals should be entered on the test report giving the total number for animals presented without identification.

**Where <10% or 10 animals maximum, over 6 weeks of age, in the herd are not identified then the test should be completed and the unidentified animals provided with temporary identification by the use of a brass tag. ID cards or passports should not be returned to the herdowner until all eligible animals are properly tagged.**

**Where >10% or 10 animals maximum, over 6 weeks of age, in the herd are not identified** then a part herd test should be carried out on identified animals only and the remainder of the herd test completed following the identification of those animals in the herd over 20 days of age. The second visit fee involved will be borne by the farmer regardless of who was due to pay the original testing fee.

On the initial day of test you should remind the herdowner of his obligation to tag animals and that he should immediately order tags for this purpose if necessary.

**Where animals over 6 weeks of age remain without plastic tags on the day of reading,** then the test report, partial or complete, and the passports/identity cards for the herd, must be forwarded to the RVO and attention drawn to the presence of incorrectly identified animal(s). The RVO will arrange to serve a restriction notice for the animals(s) involved and/or the herd as is required by law and take whatever follow-up action is appropriate.

**If you have identified, for test purposes, an unidentified animal by means of a brass tag** then, of course, no passport (identity card) may subsequently have test details certified by you until such time as you have satisfied yourself as to the correlation between the animal brass-tagged and the plastic tag number on the passport. This ordinarily will require re-visiting the herd to check the animal(s) involved.
The herdowner/keeper will be responsible for any costs involved.

Only those animals born prior to the introduction of the new plastic tag identification system may be permanently identified by means of a brass tag. It is the intention, therefore, that brass tags will, within a reasonable timeframe, cease to issue or be available except for the purpose of essential retagging of animals legally brass-tagged.

**Passports:**

Each animal born in Ireland, after 1.1.98 should have an official pre-printed passport. Obviously the description of an animal on its passport must match the animal. In addition the animal’s keeper is required to sign the passport either on the front if the animal was born into the herd or on the back if purchased. Thus, when you are checking passports at time of test be aware that the herdowner’s/keeper’s signature should ordinarily be on each passport. It is the intention that each animal’s passport will accompany it throughout its life to facilitate completion of a full traceback for consumer protection, fraud prevention, disease control etc. Great care must be taken therefore, to ensure that passports are not lost or mislaid while in your possession.

**Farm inspections under the Identification Regulations:**

The EU regulations mentioned above also require the competent authority to conduct inspections of a minimum of 5% of holdings, to monitor compliance with the regulations. Operational details for these inspections are currently being finalised. In some instances the RVO may arrange inspections to coincide with TB or other tests being conducted on a herd. Registration records, passport details and entries on the herd register will be checked during these inspections in addition to individual animal tagging. Maintenance of national eligibility for export and other outlets for cattle and meat products and for various EU premia is dependent on compliance with all identification regulations. Therefore, you are advised as part of the general service to your clients to draw their attention to any deficiencies in this regard, that you may observe while on their holdings.

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**ER Circular 16 /2008 Rev 1.**

**Issue date:** 3rd November 2008.

**Effective date:** - Issue Date

**To the SVI/HEO/DS at each RVO**

**Copy to each SSVI/RAP**

**Subject:** Bovine Identification and the use of Brass Tags

**Purpose**

To standardise the manner in which RVOs correlate brass tags used to temporarily identify bovine animals at the time of testing with the animals’ proper plastic tag identification.

**Policy**

Circular ER6A/2000 that issues annually with the ER4 instructions to all testing PVPs and WTVIs sets out the procedures relating to the treatment of bovines that have been temporarily identified with brass tags. The basis of the veterinary certification contained in that Circular has not changed viz “if the testing vet has identified, for test purposes, an unidentified animal by means of a brass tag then, of course, no passport (identity card) may subsequently have test details certified by the testing vet until such time as they have satisfied themselves as to the correlation between the animal brass-tagged and the plastic tag number on the passport. This ordinarily will require re-visiting the herd to check the animal(s) involved. The herdowner/keeper will be responsible for any costs involved.”

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Legislation


Procedures

The AHCS discrepancy report highlights tests where brass tags have been used to temporarily identify animals for the purpose of the test. The ER96 (copy attached) has been revised and is now divided into two sections as follows:

- **Section A:** signed declaration by the keeper regarding the correlation of temporary brass tags with the permanent identity contained on plastic tags.
- **Section B:** signed declaration by the testing veterinary surgeon that the correlation is correct and that he/she can certify the TB and/or Br test.

If the keeper submits the ER96 and **Section A only** is completed then the discrepancy flag on the AHCS can be lifted by using the facility on the AHCS Edit Animal screen to record the keeper declaration for the temporary tagnumber. Where relevant, the discrepancy flag should also be removed from the permanent tagnumber (in accordance with Council Regulation 1760/2000 the keeper is the person legally responsible for identifying the animal).

If the testing Practitioner has also completed **Section B**, then the test details may also be updated on AHCS using the Correlate Tags screen and the animal’s passport, if in the RVO, can be returned to the PVP for updating the test details.

The paragraph in the discrepancy letter that refers to animals temporarily tagged has been modified to take account of the changes made to the ER96. A copy of the ER96 should always accompany the discrepancy letter.

The revised ER96 form is now available on the Ezone and all copies of the old version should be withdrawn and destroyed immediately. Supplies of the revised version should also issue to PVPs so that they have copies available to give to the keeper at the time of the test.

The following are the procedures for dealing with animals temporarily tagged at test or indeed animals withheld from test:

1. Details of un-correlated temporary tags (i.e. no ER96 submitted) can be identified by running discrepancy reports for the herd in question.
2. All surplus passports should be forwarded to RVO: this includes passports for animals temporarily tagged at test which are not the subject of an ER96 counter-signed by the testing VS and any animals not presented for test.
3. VS should **not** retain passports for animals not tested or not presented for test.
4. Passports should be held in the RVO until **Section B** on the ER96 has been completed by the testing VS.
5. For unregistered animals temporarily tagged at test that will be the subject of a late registration, check that all temporary tags used in the herd have been correlated and that the correlation has been certified by the testing VS, prior to authorizing the issue of a passport.

**Key Words:** Brass tags, PVPs, Keepers and ER 96

**Authorised by:** ERAD Management Committee

**Date:** November 2008
Appendix 2.4  NOTES ON COMPLETION OF PRE PRINTED ER15B

1. In column headed ‘Breed’ the following entries only should be used:

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<td>MA</td>
</tr>
<tr>
<td>Montbelliarde</td>
<td>MO</td>
</tr>
<tr>
<td>MRI/MRY</td>
<td>MY</td>
</tr>
<tr>
<td>Murray Grey</td>
<td>MG</td>
</tr>
<tr>
<td>Normande</td>
<td>NO</td>
</tr>
<tr>
<td>Norwegian Red</td>
<td>NR</td>
</tr>
<tr>
<td>Parthenaise</td>
<td>PT</td>
</tr>
<tr>
<td>Piemontese</td>
<td>PI</td>
</tr>
<tr>
<td>Romagnola</td>
<td>RM</td>
</tr>
<tr>
<td>Rotbunte</td>
<td>RB</td>
</tr>
<tr>
<td>Salers</td>
<td>SA</td>
</tr>
<tr>
<td>Shorthorn</td>
<td>SH</td>
</tr>
<tr>
<td>Simmental</td>
<td>SI</td>
</tr>
<tr>
<td>South Devon</td>
<td>SD</td>
</tr>
<tr>
<td>Swedish Red</td>
<td>SR</td>
</tr>
<tr>
<td>Wagyu</td>
<td>WA</td>
</tr>
<tr>
<td>Ayshire</td>
<td>AN</td>
</tr>
<tr>
<td>Bainette</td>
<td>BI</td>
</tr>
<tr>
<td>Belgian Blue</td>
<td>BB</td>
</tr>
<tr>
<td>Black Face</td>
<td>BF</td>
</tr>
<tr>
<td>Blone D’Aquitane</td>
<td>BA</td>
</tr>
<tr>
<td>Brown Swiss</td>
<td>BS</td>
</tr>
<tr>
<td>Charolais</td>
<td>CH</td>
</tr>
<tr>
<td>Chianina</td>
<td>CI</td>
</tr>
<tr>
<td>Danish Red</td>
<td>RD</td>
</tr>
<tr>
<td>Dutch Red</td>
<td>DR</td>
</tr>
<tr>
<td>English Red</td>
<td>ER</td>
</tr>
<tr>
<td>Finn Red</td>
<td>FR</td>
</tr>
<tr>
<td>Girgentina</td>
<td>GI</td>
</tr>
<tr>
<td>Grey Face</td>
<td>GF</td>
</tr>
<tr>
<td>Guernsey</td>
<td>GU</td>
</tr>
<tr>
<td>Hanover Red</td>
<td>HR</td>
</tr>
<tr>
<td>Hereford</td>
<td>HE</td>
</tr>
<tr>
<td>Holstein/Friesian</td>
<td>FR</td>
</tr>
<tr>
<td>Irish Maol</td>
<td>IM</td>
</tr>
<tr>
<td>Jersey</td>
<td>JE</td>
</tr>
<tr>
<td>Jersey Red</td>
<td>JR</td>
</tr>
<tr>
<td>Jersey White</td>
<td>JW</td>
</tr>
<tr>
<td>Kerry</td>
<td>KE</td>
</tr>
<tr>
<td>Krim Red</td>
<td>KR</td>
</tr>
<tr>
<td>Limousin</td>
<td>LM</td>
</tr>
<tr>
<td>Limousin Red</td>
<td>LR</td>
</tr>
<tr>
<td>Limousin White</td>
<td>LW</td>
</tr>
<tr>
<td>Livrard</td>
<td>LV</td>
</tr>
<tr>
<td>Maine Anjou</td>
<td>MA</td>
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<tr>
<td>Maine Anjou</td>
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<td>Maine Anjou</td>
<td>MA</td>
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<tr>
<td>Maine Anjou</td>
<td>MA</td>
</tr>
</tbody>
</table>

In the case of a breed not listed please record the full name. Cross Breeds should be entered with an X after the dominant breed, e.g. HEX for a Hereford Cross.

2. All animals should be presented with two plastic ear tags for identification purposes. In the case of plastic tags containing an alpha-numeric identifier, the tag number should be written in the format: Letters: numbers: check digit e.g. BEA 19731-4 or Letters: numbers: check letter e.g. BCDF 0025Y. The tag number of plastic tags containing an all-numeric identifier should be written in the order in which the numbers appear on the tag. All zeros included in the number must be recorded. Normally the full space allocated should be used for recording an animal’s tag number.

The tag space itself is partitioned into top and bottom halves to facilitate a double entry where a temporary tagging for test ID purposes takes place. The temporary tag number should be entered on the lower space and the permanent tag number (i.e. where the old tag or passport/animal ID card is available) is entered on the top line. In cases where the permanent identity of the animal is not known leave the top line blank. Where a temporary brass tag is inserted record TT in the Tag/Pass column. Brass tagging of animals for temporary identification for test purposes, is only allowed where <10% of herd require such. Otherwise return to complete test after farmer has regularised the identification of the animals. Correlation of temporary tag with permanent identification number, is required before any test certification may be completed on individual passport/animal I.D. card, export certificate etc. See letter Ref: 6A/2000 for details.

3. Tag/Pass - The absence of identification documentation (Passport/ID Card) should be indicated by:

- (i) NC No Card ----- Or (ii) FC Full Card ------ Or (iii) WC Wrong Card

Where a temporary tag was used to identify the animal TT should be inserted.

4. Age/DOB should be recorded in the following order – year/month or actual age.

- e.g. 1/0 one year old 1/6 one year and six months 0/10 ten months

5. The following codes should be used for recording the sex of the animal:

- Cow C
- Bull B
- Heifer H
- Bullock/Steer S

If an animal is pregnant state the length of pregnancy (e.g. C4 = cow pregnant 4 months).

6. The column headed ‘Clinical Remarks’ is intended for recovering conditions relevant to both TB and Brucellosis testing. In the case of TB the following clinical conditions should be recorded if present:

- Cough CO
- Emaciation EM
- Snoring SN
- Enlarged lymph glands GL

In the case of Brucellosis blood testing any abortion history (i.e. date of abortion) should be entered.

7. In the column headed ‘Reaction’ the following are the appropriate entries.

- (i) Diffuse Oedema D.O. (ii) Extensive Oedema E.O. (iii) Circumscribed C.

8. In the column headed ‘Result’ you should indicate the result of both increases. In the column headed ‘Test Result’ you should indicate the overall result of the test:

- (i) Positive + Or (ii) Doubtful 0 Or (iii) Negative --

The column headed ‘BR Tested’ must be completed where a prepared list of the animals to be tested is provided by the D.V.O. If an animal has been blood tested the letter ‘Y’ should be inserted in this column to indicate that the animal was blood tested.
APPENDIX 2.5

S.O.P. for PVP Supervision by V.I. 2016

1. Preparation

VI's who carry out PVP supervisions must be aware what version of the software is approved and must be competent/comfortable with interrogation of hand held electronic test recording devices.  

Print off and retain a copy of advanced itinerary using fixed queries on AHCS.  PVP is obliged to adhere to detailed itinerary submitted via ER9 or electronically and failure to do so may require that supervision is rearranged for an alternative date at the expense of the PVP.  

Check most recent date of download of the herd profile by/for the PVP  

Inspections should be unannounced on injection or reading day with a target of 100 and a minimum of 50 animals.  

Time of inspection to be based on advanced itinerary submission. Emergency changes in reading time must be notified by dedicated e-mail prior to test reading. A VI may arrive at a farm up to 1 hr prior to the time recorded on the advanced itinerary and may be required to stay on farm up to 4 hrs.  

If PVP has read the test/s at a time prior to the time on advanced itinerary or can cancel without notification it is a major non compliance under ER4 (point 1.3); an inspection charge (administrative sanction) to be applied based on ER03/10 with re inspection to be completed within 30 days. This inspection should be documented with a comment for the record and recorded as inconclusive on AHCS.  

In the case of a test completion inspection where the animals have already read by the PVP prior to the VI(s)’s arrival the VI(s) will inspect approximately 30 animals (or the whole herd) and carry out a reading and recording of any reactions observed. The records of animals with reactions and the size/nature of those reactions will be then compared with the contemporaneous records of the PVP.  

If findings, other than compliance with the ER9 time element, indicate satisfactory testing a non compliance (moderate) should be raised with charge and re inspection. PVP must be immediately notified of non compliance disclosed.  

In case of farmer non co-operation, cross compliance, invalidation and prosecution may be pursued (under 2013 Animal Health and Welfare Act (No. 15 of 2013) and Animal Health and Welfare (Bovine Tuberculosis) Regulations – note S.I. 58 of 2015 Regulation 8(2)(b) requires the keeper or herdowner to assemble animals for inspection and Regulation 29 is also applicable. Regulations 8 and 29 are penal provisions).  

2. On Farm Inspection ER13 of test performance (i.e. on the physical act of testing)  

The VI(s) will introduce themselves to the farmer and the PVP. If not personally known to PVP/farmer the VI will present official identification and in any event will present it if requested. A copy of the information note (ER13i ) will be given to the PVP outlining the purpose of the inspection.  

The VI will inform PVP that supervision is being conducted to ensure compliance with terms and conditions of the contract to conduct tuberculin testing and/or sampling under the bTB and/or other national eradication or monitoring programmes as laid down in the ER4 and legislation (EU and National) pertaining to conduct of testing and the standards for same laid down by OIE.  

In very exceptional circumstances a case may be made for covert surveillance of testing to the SSVI of the Regional Area Management Team.  

Observations made on approach and/or prior to VI introduction must, in any event, be included in the ER13 as if the introduction had been made.  

- Compliance with ER4 field requirements  

The results of the inspection will be recorded on forms ER13 and ER13b. Any deviation from biosecurity, equipment and testing procedure requirements should be recorded on form ER13. An audit of testing procedure at animal level will take place on a minimum of 10 animals and the results will be recorded on form ER13b  

- Testing technique  

Supervision of a target of 100 and a minimum of 50-animals is required – this may of necessity extend beyond one herd - (assess reading/recording tag number, injection site location, site identification [clipping], record of any site anomalies, taking and recording of measurement and on day 1 injection technique. The injection site should be in the correct location and clearly visible, a fold of skin within the clipped area should be palpated prior to injection to ensure no adhesions to subcutaneous tissues or abnormalities within the dermis at the proposed injection site and following intradermal tuberculin
injection a pea should be palpable noting that both Directive 64/432/EEC and the OIE each require that a correct injection is/shall be “confirmed by palpating a small pea-like swelling at each site of injection”.

**Failure of PVP to demonstrate the ability to inject tuberculin intradermally and raise a pea like swelling at each site on each animal is a major non compliance and the test should be suspended pending completion by another practitioner.**

1. **On Day 1 inspection the VI must inform the PVP that the testing technique for the first 5 animals supervised will be for observation and feedback purposes and will not normally be included on the ER13B report. The VI will inform the PVP of any deficiencies observed on the first 5 animals and instruct the PVP as to the correct technique in compliance withER4 instructions. These observations must be noted on the ER13 report. The VI will then inform the PVP that the ER13B will be completed for the next consecutive 10 animals presented for testing. Compliance with the following animal level criteria; animal identification, site location, site preparation, skin fold measurement and pea confirmation will be recorded.

2. **On Day 2 inspections the VI will be required to select 10 consecutive animals and record compliance with animal level testing criteria on form ER13B i.e. animal identification, site location, clipping, palpation, measurement and recording of the nature and type of reaction.**

**Compliance rating will be based as follows;**

**Day 1**
- Identification, site location, clipping, confirmation of pea and measurement all compliant in >90% of animals : Pass
- Identification, site location, clipping, confirmation of pea and measurement all compliant in 80-90% of animals: Inconclusive; Moderate non compliance
- Identification, site location, clipping, confirmation of pea and measurement all compliant in <80% of animals: Fail; major non compliance

**Day 2**
1. Identification, site location, and clipping, palpation and measurement all compliant in >90% of animals : Pass
2. Identification, site location, and clipping, palpation and measurement all compliant in 80-90% of animals: Inconclusive; Moderate non compliance
3. Identification, site location, and clipping, palpation and measurement all compliant in <80% of animals: Fail; major non compliance

- **Examination of Fieldbook/Hand held Recording Device – VI will check:**
  - Software version and record on ER13
  - Correct PVP code - as on advance itinerary and testing PVP
  - Correct date
  - Use of current herd profile as on ER9
  - Tuberculin Batch recorded i.e. individual batch number on each vial (avian and bovine) or the individual code on the ‘kit’ containing the avian and bovine vials.
  - Animal IDs /skin measurements
  - Blood tube codes recorded if appropriate (Note: PVPs do not conduct official blood sampling for TB)
  - Batch identification for groups of animals – to include location if animals not all tested at same location (important for any subsequent epidemiological investigations to identify cohorts as necessary and legally required under Regulation 8(8)(b) of SI 58/2015)
  - Number of animals tested and animals awaiting test data
  - Untested or unread at 72hrs
  - Date for previous herds examine data
  - Profile discrepancies queried with keeper and recorded

**Recording of all animals presented for test and testing of properly identified animals (CCP 1):**
All animals must be recorded with day 1 readings on handheld or ER15B; and all animals must be recorded with second day readings day 2. Failure to record measurements for all animals tested is a
major non compliance (untested homebred calves <6-weeks of age do/should not have skin measurements/readings recorded).

Check untested animals at end of the test
  o if present on farm and not recorded - major non compliance,
  o if recorded absent, review PVP comment; if no commented - minor non compliance;
Check animals recorded as tested based on inspection;
  o failure to record day 1 or testing of unidentified animals; major non compliance
Examine records for previous tests; major non compliance if day 2 readings not entered for day 1 recorded animal/s.

Refusal to surrender records for examination is a major non compliance. PVP should be warned that failure to surrender field book or recording device is an offence under 2013 Animal Health and Welfare Act (No. 15 of 2013) and Animal Health and Welfare (Bovine Tuberculosis) Regulations – and may lead to prosecution.

Clinical remarks not recorded is moderate/minor non compliance

VI will evaluate instructions/advises given to farmer by PVP in response to questions and/or the event of reactors or inconclusive reactors being disclosed (compatible with ER4 Instructions on isolation of reactors, withholding of milk and movement prohibitions).

VI will inspect the supply of spare tags for use on unidentified animals.

4. Findings

i. In normal circumstances minor non compliances which do not compromise the validity of the test should be, discretely, brought to the attention of the PVP as they arise and recorded by VI on ER13

ii. Moderate non compliances which do not compromise test certification will result in an inconclusive result for the inspection and consequential follow up in accordance with Circular 03/2010.

iii. Major non compliances may lead to all or part of the test being declared null and void and therefore herd restriction pending repeat of test (Minimum 6-week inter-injection interval in case of TB). In such circumstances the VI will explain the position to the farmer. A fail supervision report must be submitted and followed up in accordance with Circular 03/2010.

iv. PVP will be offered an opportunity to insert comments on the ER13 and requested to sign the ER13 and ER13B.

v. A copy of the completed ER13 will be given to the PVP at the completion of the inspection and a copy of ER13B will be forwarded if requested.

Please note: In the case of a test completion inspection where the animals have already been read by the PVP prior to the VI(s)’s arrival the VI(s) will inspect approximately 30 animals (or the whole herd), complete the ER13B and carry out a reading on any reactions observed. Each individual’s calliper measurements in mm are unique to that individual and consequently will not necessarily be identical the records of animals with reactions and ‘size’/nature of those reactions, will be compared with the contemporaneous records of the PVP. There should be no delay in attempting to obtain the records from the PVP. Since the physical performance of the test was not observed no ER13 will be completed in such cases.
### Appendix 2.6 ER13 Field Inspection Report

**Department of Agriculture Food and the Marine**

**Report of on-farm supervision of Testing under Tuberculosis Eradication Programme**

<table>
<thead>
<tr>
<th>A.</th>
<th>Supervision</th>
<th><em>Announced/Unannounced</em></th>
<th><em>Yes/No</em></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Is the planned PVP present as on the advanced itinerary ER9</td>
<td><em>Yes/No</em></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Planned Date</td>
<td>Actual date</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Planned Time</td>
<td>Actual time</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Planned PVP Code</td>
<td>Actual PVP code</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Was test completed within 72+/4hrs of commencement</td>
<td><em>Yes/No/NA</em></td>
<td></td>
</tr>
</tbody>
</table>

### B. Equipment check

1. Three properly functioning syringes (including spare) | *Yes/No* |
2. Identification of Avian (red) and Bovine (blue) Syringes | *Yes/No* |
3. Individual syringe identification | *Yes/No* |
4. Spare Needles, needle adaptor. | *Yes/No* |
5. Appropriate supply of Bovine/Avian tuberculin | *Yes/No/NA* |
6. Functioning callipers | *Yes/No* |
7. Clippers and/or sharp scissors | *Yes/No* |
8. Taggers, Reactor Discs, temporary and Reactor Tags | *Yes/No* |
9. Thermometer and stethoscope for clinical examinations | *Yes/No* |
10. Surgical spirits and cotton wool | *Yes/No* |
11. Holsters used for holding syringes | *Yes/No* |

### C. Test Procedures

<table>
<thead>
<tr>
<th>Procedure</th>
<th>ER13B completed</th>
<th><em>Yes/No/NA</em></th>
</tr>
</thead>
</table>

**SICTT**

a) Tag numbers recorded for all animals day 1 | *Yes/No* |

b) Skin measurements recorded for all animals day 1 | *Yes/No* |
c) Callipers used in measuring all animals: | *Yes/No* |
d) Tag numbers recorded for each animal 72hrs | *Yes/No/NA* |
e) 72nd hour skin measurements recorded for each animal: | *Yes/No/NA* |
f) Location of injection sites: | *Satisfactory/Unsatisfactory* |
g) Clipping of injection sites: | *Satisfactory/Unsatisfactory* |
h) Was the 'pea' confirmed after injection? | *Yes/No/NA* |
i) Was the nature of the 72nd hour reaction recorded? | *Yes/No/NA* |
j) Presence of so-called Skin T.B. or other swellings noted and recorded? | *Yes/No/NA* |
k) Reactor(s) identified and tagged. | *Yes/No/NA* |

**Test procedures (ER13B)** | *Pass/Fail/Inconclusive* |

### Test recording

<table>
<thead>
<tr>
<th>Procedure</th>
<th><em>Yes/No</em></th>
</tr>
</thead>
</table>

a) Field book/ER15B as appropriate (as back-up even if electronic recording) | *Yes/No* |
b) Electronic recording. | *Yes/No* |
c) Approved software. | *Yes/No/NA* |
d) What version of software used | *Yes/No/NA* |
e) Field Book/ER15B/Herd profile used | *Yes/No* |
f) Field book recording device tendered to VI on request | *Yes/No* |
g) Refusal to tender hand held/field book (insert comments in results section) | *Yes/No* |
h) Field book/hand held examined, initialled and faults noted in respect of Herd/s inspected | *Yes/No* |
i) Field book/hand held examined, initialled and faults noted in respect of previous Herds | *Yes/No* |

**Test recording** | *Pass/Fail/Inconclusive* |

a) Completed ER11 signed by farmer and witnessed? | *Yes/No/NA* |
b) Passports/Identity Cards taken up at the commencement of test? | *Yes/No* |
c) Test date entered on passports/identity cards (check ID documents that may be in PVP’s possession for return to any herd) | *Yes/No* |
d) All animals on profile accounted for? | *Yes/No* |
**Bio-Security:**

<table>
<thead>
<tr>
<th>a)</th>
<th>Protective clothing worn by VS – Rubber boots?</th>
<th>Satisfactory/Unsatisfactory</th>
</tr>
</thead>
<tbody>
<tr>
<td>b)</td>
<td>Was cleaning and disinfection satisfactory on arrival and departure from farm?</td>
<td>Yes/No</td>
</tr>
<tr>
<td>c)</td>
<td>Approved Disinfection available and used?</td>
<td>Yes/No</td>
</tr>
<tr>
<td>d)</td>
<td>Keeper instructed to isolate reactors and withhold milk from human and animal food chain</td>
<td>Yes/No/NA</td>
</tr>
</tbody>
</table>

**Bio-security**

Pass/Fail/Inconclusive

**Blood Sampling (If applicable):**

<table>
<thead>
<tr>
<th>a)</th>
<th>Was the field book or other recording method properly completed?</th>
<th>Yes/No</th>
</tr>
</thead>
<tbody>
<tr>
<td>b)</td>
<td>If samples were taken prior to inspection commencing, are an appropriate number of the used needles held for safe disposal?</td>
<td>Yes/No</td>
</tr>
<tr>
<td>c)</td>
<td>Were all samples properly labelled and correlated to the ear-tag number of the animals sampled</td>
<td>Yes/No</td>
</tr>
</tbody>
</table>

**E. Results:**

<table>
<thead>
<tr>
<th>a)</th>
<th>Punctuality</th>
<th>Pass/Fail/Inconclusive</th>
</tr>
</thead>
<tbody>
<tr>
<td>b)</td>
<td>Equipment</td>
<td>Pass/Fail/Inconclusive</td>
</tr>
<tr>
<td>c)</td>
<td>Test procedures (Result of ER13B)</td>
<td>Pass/Fail/Inconclusive</td>
</tr>
<tr>
<td>d)</td>
<td>Test recording</td>
<td>Pass/Fail/Inconclusive</td>
</tr>
<tr>
<td>e)</td>
<td>Bio-security</td>
<td>Pass/Fail/Inconclusive</td>
</tr>
</tbody>
</table>

**Overall supervision inspection result**

*Pass/Fail/Inconclusive*

V.I. comments

__________________________________________________________________________
__________________________________________________________________________
__________________________________________________________________________

Signed: ___________________________ (V.I.)  Date: ________________

V.I. Code: _____________________  Date: __________________

Signature of PVP __________________________________________________________________________
PVP comments: __________________________________________________________________________

________________________________________________________________________________________
________________________________________________________________________________________
________________________________________________________________________________________

**F. Recommendations:**

Recommendations by SVI: __________________________________________________________________________

________________________________________________________________________________________

Signed _____________________________ Date ________________

Recommendations by SSVI: __________________________________________________________________________

________________________________________________________________________________________

Signed _____________________________ Date ________________

Copy to PVP on completion of inspection. Original for Retention by R.O.
Appendix 2.7 Guidelines for TB Inspection of Veterinary Practice.

The purpose of the TB inspection of a Veterinary Practice is to ensure compliance with ER4 testing instructions particularly in relation to certification, equipment, passport management and Tuberculin.

1. Preparation
   • A Practice Users Activity Report for the month prior to the inspection and copies of recent ER13A reports for all PVPs in the practice should be brought by the inspecting officer.
   • Inspections should be pre-arranged so as to ensure the presence of the appropriate clerical staff and at least one PVP.

2. Equipment
   Examine any syringes available for working condition and identification. Syringes found to be defective should be sent for servicing.

3. Tuberculin
   Ensure that Tuberculin is stored at the recommended temperatures. 2-8°C. Out of date Tuberculin should be returned to the DO by the inspecting officer.

4. Hand held test recording devices
   The make/model and software version should be recorded on the inspection sheet.

5. AHCS Procedures
   The inspector should request demonstration by clerical staff and PVP of AHCS test processing procedures with particular attention to correct code usage and security by each party. Findings should be recorded on the form with comments where appropriate. The practice usage report should be discussed with the PVP and clerical staff. Anomalies should be followed up by way of written warning. Administrative and disease related anomalies found on the ER13A reports should also be discussed.
   Re-inspection should take place where certification is found to be compromised.
## Appendix 2.9 TB Practice Inspection Report

### TB ER13P

<table>
<thead>
<tr>
<th>Practice Name</th>
<th>Address</th>
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</thead>
<tbody>
<tr>
<td></td>
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</table>

<table>
<thead>
<tr>
<th>Date of Visit</th>
<th>Number of PVPs Engaged</th>
<th>Name of PVPs present at time of visit</th>
<th>Number of clerical staff involved in TB</th>
</tr>
</thead>
<tbody>
<tr>
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</table>

**Tuberculin Storage**

<table>
<thead>
<tr>
<th>Refrigerated at correct temperature (2-8°C) Y/N</th>
<th>All Tuberculin in date Y/N</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
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</tbody>
</table>

**Syringes**

<table>
<thead>
<tr>
<th>Number examined</th>
<th>All syringes Individually Y/N</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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**Hand held devices**

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**AHCS Procedures**

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**Certification issues**

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**Inspecting Official**

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**Admin**

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APPENDIX 3

Tuberculosis Epidemiology: ER76 Investigations

Guidelines for Veterinary Inspectors

Objectives
i. Assess reactors, their reactions and the regression pattern (appendix 3a), sample them for IFN-\(\gamma\) QC purposes and assess the degree to which collective results or these checks indicate TB infection (see also Section 9).

ii. Ensure reactors are isolated and identify all areas where cleansing and disinfection is required.

iii. Identify possible and probable sources of \(M.\ bovis\) infection in the herd.

iv. Check classification of the breakdown (Section 6).

v. Identify possible cohort groups of animals in the herd which are likely to be the focus of infection (removal of additional animals, severe I/R, SIT positive, group removal, confinement – ER84).

vi. Advise the keeper on appropriate disease control measures to be taken during and after the breakdown for outbreak management. Also check that milk is being withheld and not supplied for human consumption (only suitable for feeding existing reactors).

vii. Advise the keeper on the zoonotic implications for the family, farm workers and others potentially exposed and on the best course for management of the outbreak to minimise the risk of zoonotic exposure.

viii. Identify and risk categorise animals for forward tracing (Section 12).

ix. Identify herds for inclusion in the contiguous programme (Section 10).

x. Arrange sampling of the relevant cohort group (4 above) for IFN-\(\gamma\) assay with the keeper in accordance with policy (see Section 8 and appendix 3) when TB infection is indicated following 1 above.

xi. Check that DAFM requirements re herd register are being adhered to and that tracing is therefore accurate and

xii. Provide data for the analysis required for policy formulation.

xiii. If bovine origin infection is unlikely or ruled out and if badger involvement is suspected, the VI will check for evidence of badger activity relevant to the infected cohort to refer to the wildlife unit.

Preparation
When a VI receives a request to carry out an ER76 investigation on a herd he/she should ensure that the “Travel Pack” contains the following:

a) Herd test history and animal test history as on AHCS ER76

b) ER 35

c) Herdfinder map

d) Wildlife map with setts (if available)

e) ER128 Forward trace list

f) Back-trace report now part of ER76 on AHCS

g) Discrepancy report ER24 and AIM profile

The VI should acquaint him/herself with the information in the “Travel Pack”.

The visit should be by appointment.

The Keeper should be advised to have available he following:

- Herd register
- Area aid orthography or LPIS maps of the farm
- 60-90 minutes of time to spend on the consultation

The VI should check the current disease status of the contiguous herds (on ER 35 list) and previous herds, if there are introduced reactors, and animal test history for animals present during a previous episode in this or another herd and as far as possible endeavour to ascertain if any animals were previously part of an infected grouping.
On Farm Consultation

a. The VI should give a brief explanation of the purpose of the visit to the Keeper

b. The VI should use the ER 76 form as a framework for the consultation and to record the information gathered in the course of the consultation. The VI should establish the group structure of the herd. Work through the grazing, housing pattern and animal groups with the keeper. The VI should check the testing order of the animals at the most recent tests in order to determine the most recent group composition in the herd and to aid in selecting animals for cohort IFN-γ assay

c. Establish the number of fragments on the farm and define the infected and non-infected fragments. Select herds for inclusion in contiguous programme.
d. Go through the ER 35 form and fill columns 5 & 6. Carry out a spot check of the boundary fence for overall quality and areas where nose-to-nose contact might occur.
e. Fill the badger section.
f. Determine the animals for “H” and “D” classification.
g. NB In designating a “H” status to an animal for onward tracing the VI should apply the following definition:
   An “H” category animal is an animal that, in the opinion of the investigating VI, is likely to fail a TB test in its present location
   h. Inspect yards, housing, feed stores and water troughs and advise re biosecurity
   i. Record advice given to keeper and invite keeper to offer observations and to sign the relevant section of the ER 76 for

Follow up

a. Report to SVI and request a badger survey if the investigation indicates that a badger survey is justified.

b. Completed VI ER76 checklist

c. Complete report on AHCS/AFIT .
APPENDIX 3(a)

Normal Regression of skin fold increases post Tuberculin injection.

- A: animals with skin fold increases > 20 mm at day 3
- B: animals with skin fold increases between 10 and 20 mm at day 3
- C: animals with skin fold increases < 10 mm at day 3
APPENDIX 3(b)

Circular: ER 06/2016
Date: 17 May 2016
To: AMTs, RVO SVIs, HEOs, DSs

Subject: Protocol for Strategic applications of the IFN-γ assay in reactor herds

To lay down criteria for Strategic applications of the IFN-γ assay in TB restricted herds.

1. Policy

It is stipulated in Directive 64/432/EEC and recommended by the TB task Force and by the FVO that to enable the detection of the maximum number of infected and diseased animals in a herd the IFN-γ assay should be carried out in addition to the SICTT. IFN-γ assay is to be applied as a quality control measure on SICTT reactors and as a diagnostic aid in breakdown herds. VI/SVIs are the managers of TB episodes in herds and are therefore responsible for implementation of policy. All sampling should be undertaken under the instruction of the VI/SVI.

2. Target Herds/animals

A. SICTT Reactor IFN-γ assay

i. Herds in which 3 or more reactors are disclosed at any test (including reactor retests) should have 24 hour IFN-γ assay carried out and reactors assessed by a VI as per ER06/09 protocol. Where 2 SICTT reactors have been disclosed at a test TAOs should carry out 24 hr sampling. Herds with one reactor should be sampled opportunistically during the course of other duties.

ii. Results following 24hrs IFN-γ assay should be evaluated using the data recorded on the reactor assessment form during the farm visit in relation to injection site location, nature and size of reactions, regression pattern viz. a viz. SICTT reading reported at 72-hrs, and results of 24hr IFN-γ assay. Investigations involving poor correlation between SICTT and IFN-γ assay should be managed on a case by case basis using the 24hr gamma test results in conjunction with the information recorded by the VI on examination of the SICTT injection sites while blood sampling the animals. Where the validity of the SICTT result as submitted is in doubt the investigation should, in the first instance include 8hr gamma sampling of reactor animals. In cases of incorrect SICTT site location follow up should also include PVP supervision whether or not the validity of the SICTT result as submitted is being investigated. Where there is abnormal SICTT injection site regression validity of the SICTT should also be considered. In the case of animals nominated as reactors to the SICTT it is expected that there is normally over 80% correlation between the SICTT and the 24hr IFN-γ assay results with higher IFN-γ bovine bias for standard reactors and lower for standard inconclusive, severe inconclusive and bovine only SICTT readings. One of the most common reasons for lack of correlation between the reported SICTT readings and the IFN-γ readings/result is that the avian tuberculin injection was made too close to or on the crest of the neck and/or too far back onto the shoulder (or both in combination) – such sites are unresponsive to tuberculin so that coupled with an adequate bovine site the animal may only be a reactor to the Single Intradermal Test.

iii. The degree of correlation between animals reported as SICTT reactors and 24hr IFN-γ positive assay has generally raised to over 85% since QC-gamma for reactors commenced. This reflects an improvement in the performance of the SICTT generally and penetration of an understanding that cull animals volunteered as reactor will be rejected causing embarrassment to PVP and farmer alike. Thus even in cases where between 4 and 10 SICTT reactors are reported it is expected that there should be over 80% correlation with the 24hr IFN-γ assay noting that 3 of 4 cannot be higher than 75%. Where there is less than 70% correlation the VI must have regard for the assessment of the injection sites, reported skin test readings, the nature, location and regression pattern of the injection sites and the IFN-γ assay readings. The VI having considered the totality of the investigation should consult the SVI with a view to carrying out 8 hour IFN-γ assay on all the SICTT reactors. As SICTT reactor numbers increase it becomes relatively easier to determine an acceptable correlation. Where there are more than 10 SICTT reactors and there is less than 80% correlation with 24 hour IFN-γ assay all of the SICTT reactors should be subjected to 8 hour IFN-γ assay before a decision is made on whether to remove any, some or all of the reported SICTT reactors. ERAD veterinary HQ should be consulted in such cases. Where a decision is made not to
remove all or some of the reported SICTT reactors and to submit them to further investigation they should be isolated, the herd restricted, passports withheld and the animals subjected to a SICTT by a VI after 42 days. The animals should not be permitted to slaughter in the interim.

B. Cohort IFN-γ assay in breakdown herds

i. Notwithstanding the general apparent improvement in SICTT performance it remains appropriate that sampling for IFN-γ assay should be promptly undertaken in herds with TB-outbreaks in or from which 4 or more positive animals have already been disclosed in order to ensure that, in so far as is possible, the maximum number of infected animals are disclosed, removed and the total duration of the TB-outbreak, the risk of development of latency causing repeat breakdown, and of onward movement of TB infected animals is reduced. This sampling refers to non-reactor animals for ‘same-day’ assay i.e. whole groups of cohorts to reactors/infected animals or balance of herd as determined relevant and at risk of exposure by the investigating VI. It is preferable that samples are taken 10 or more days post tuberculin injection i.e. normally the week following the QC 24-hr gamma on reactors.

ii. IFN-γ sampling is to be prioritized in breeding herds (i.e. excepting feedlots, fattening/non-breeding groups and/or where the VI is satisfied that the TB did not originate in the herd of reactor disclosure and there is no evidence of within herd spread) where:

a. there are four(4) or more positive animals in a breakdown: note: this will include a combination of skin reactors, factory lesions and/or back-traced reactors/factory lesions,

b. disclosure of further skin reactors and/or factory lesions at a third and/or any subsequent reactor retest (other than herds that have been determined to be ‘Atypical’ and where laboratory examination of tissues from reactors has not confirmed TB or where all reactors have been determined to have been infected elsewhere prior to entering the herd of disclosure and have gone reactor on the first test in the present herd),

c. 24 hr IFN-γ QC correlation of skin reactors is abnormally high (i.e. approaching100%) and where in the opinion of the VI not all of the reactors may have been identified in the SICCT test,

d. TB did not originate in the herd of reactor disclosure and there are other non-reactors from the same source (cohorts) which are considered to be at risk of being also TB infected in which case sampling will ordinarily be confined to these cohorts.

Note: The V.I. should, during the course of his/her epidemiological investigation, endeavour to define the targeted animals to particular groups or those associated with particular land fragments with regard to grazing/housing with the reactor animals during the relevant period prior to detection/removal. Where it is not possible to categorise particular epidemiological groups e.g. in smaller herds, all animals aged over 1 year should be tested.

N.B. Selection of individual animals for IFN-γ based on SICTT reading does not constitute a cohort for sampling.

In cases of qualifying herds, where a VI/SVI decides that cohort sampling will not be carried out, in advance of the next reactor retest, the decision should be taken in consultation with the AMT.

Approval must be obtained in advance from ERAD Veterinary HQ prior to 8 hour sampling using form GIF AP1 form (See attachment)

Samples may be taken and submitted by either VI or TAO acting on instruction of the area VI/SVI.

3. Notification and booking of samples

The laboratory must be informed of any samples for submission during the week prior to sampling. This is necessary to ensure advanced preparation of sufficient testing kits and to avoid submissions over and above laboratory capacity. Under no circumstances is it acceptable that samples are sent to the laboratory without prior notification and it is unlikely that such samples will be processed. The laboratory must also be contacted on the day of taking the blood samples to confirm delivery. Please ensure that all calls relating to blood samples are made between 9:30am-5pm. The Herd status and the number of samples to be delivered should be clearly stated.
4. Tubes
The tubes used in the collection of the blood are the **10ml Green topped Lithium Heparin** tubes which should contain a minimum of 6mls of blood. **Any volume less than this is not sufficient to carry out the test.** Every effort should be made to ensure that each tube is full. Blood tubes can be obtained from the Gamma Interferon Lab in advance.

5. Packaging
Pathopak boxes as currently used. Available from UCD laboratory.

6. *Mode of Delivery*
The mode of delivery should be specified with estimated departure and arrival times. Samples should be transported to the laboratory as soon as possible to ensure delivery with sufficient time for sample processing on the same day as sampling. Samples should be stored at room temperature during transport.

7. Sample Identification
Submissions should, preferably be made using TB Blood test application on Husky with the also details transferred electronically to the laboratory or on the submission sheet form GIF Submission Cohorts giving the contact details of the submitting officer and the referring V.I. (See attachment)
Samples must be clearly marked with Tube code labels as issued for IFN-γ sampling. The onus will be on the sampling officer to take sufficient blood to enable testing, including if necessary repeat testing in the laboratory, to match tube numbers and tag numbers and to ensure labels and accompanying paperwork are legible and include a contact (preferably mobile) number for the sampler. Samples must be accompanied with the Herd Owner/Keeper’s name and herd number and the name of the referring /area VI when samples are taken by a TAO.

8. Submission forms
   i. The RVO Handheld recording device should be used when sampling animals and the submission of animal and tubes code details should be sent electronically to the laboratory in order to ensure convenient and accurate submission of test details
   ii. For manual recording (small numbers only please) samples from SICTT reactors should be submitted on the GIF reactor submission form
   iii. and samples from cohort animals for 8hr IFN-γ assay should be submitted using the GIF Cohort Submission form
   iv. In cases where samples from both reactors and cohorts from the same herd are being taken on the same day they should be submitted as appropriate with the reactors on the Reactor submission form and the Cohorts on the cohort submission form

NOTE: Failure to submit samples on the correct forms results in errors in attributing samples and results to the correct category of animal.

9. Results
   i. Samples are assayed on a queued basis and every attempt is made to generate results as quickly as possible.
   ii. The results positive/negative/untested will be sent back to the referring VI. Results will not be sent back to the sampling officer unless he/she is the referring VI. Readings will be sent back for 24-hr QC reactor samples so that the readings may be taken into consideration in assessing correlation and/or assessment if it is likely that other infected animals are present (2c above).
   iii. A VI/SVI must contact ERAD HQ should they NOT want to remove a IFN-γ positive animal. Otherwise all positive animals must be removed as reactors.
   iv. **Results of IFN-γ tests on all animals must be recorded on AHCS.**
**Procedure**

A minimum of 6ml of Blood should be taken in Lithium Heparin collection tubes, supplies of which can be requested in advance by the TB Diagnostics and Immunology Research Laboratory at UCD.

In order to comply with Health and Safety regulations samples should only be sent in IATA approved packaging. These can be provided on request by the UCD laboratory and should be labelled with the UCD delivery address.

Blood samples should **ONLY** be delivered to the laboratory from **Monday – Thursday** inclusive, before 1pm to Sligo RVL, Cork BTL and 5PM to UCD otherwise they will arrive too late for processing.

**Blood samples which arrive on Fridays will not be tested**

Blood samples must be accompanied with correct paperwork stating Herd Number, Tag Number, Tube number (if used), date of blood sampling, RVO and VI contact details.

**Blood samples for diagnostic investigations (i.e. to identify additional infected animals in an infected herd or group)**

a. should **NOT** be sent to UCD by post and

b. must be ‘booked in’ and have had prior approval from HQ.

Any such samples that arrive by post will not be tested.

**Contacts**

**UCD contacts**

Mairead Doyle / Kevina Mc Gill

TB Diagnostics and Immunology Research Laboratory
University College Dublin (UCD) Belfield, Dublin 4
Tel: 01-7166090. Mob: 086 1097640 Fax 01-7166091
Email: mairead.b.doyle@ucd.ie

**UCD deadlines**

One full week’s notice directly with Mairead Doyle.

UCD laboratory will accept samples for GIF testing from Monday to Thursday, and will require them to be delivered to the laboratory on prior appointment.

**Sligo contacts**

**Phone numbers**

071-91-42195
071-91-42191 (only if main no. out of order)

**Contacts**

Madeline O'Donoghue SSA (Supervisor, main contact)
Helga Keogh SA - alternative
Mary Kerrigan SA - alternative
Ger Murray SRO
Sean MacFadden Senior Technician

**Sligo deadlines**

One full week’s notice.

Sligo laboratory will accept samples for GIF testing from Monday to Thursday, and will require them to be delivered to the laboratory before 1pm on the day.

**Cork BTL contacts**

Phone numbers 021 4819900
Karina Wrigley SRO 021 4819900
Kate O Keefe SSA 021 4545377

**Cork deadlines**

One full week’s notice.

Cork laboratory will accept samples for GIF testing from Monday to Thursday, and will require them to be delivered to the laboratory before 1pm on the day.

**Revocation: ER04/2015 is hereby revoked**

Micheál Ó Raghallaigh  
Principal Officer  
ERAD Division

Margaret Good  
SSVI
Ancillary Blood testing

4(a) Test approval

Ancillary blood testing for TB must receive prior approval from HQ. Please forward all requests to ERAD HQ on the Excel application form with all the relevant data.

| Application for Approval for Ancillary Blood testing for Bovine TB |
|------------------------------------------------|---------------------|
| DVO                                           | Herd Number         |
| Application date                              |                      |
| Investigating VI                              |                      |
| Date                                          | Total animals        |
|                                               | No. Reactors         |
|                                               | No. In-contacts &/or co-exposed proposed for testing |
|                                               | No. Breeding animals in proposed group |
| Previous gFPN No. sampled                     | No. Positive         |
|                                               | No. removed          |
| Breakdown test                                |                      |
| 1st reactor retest                            |                      |
| subsequent reactor retest                     |                      |

Herd description:

SVI Comments

Date:

HQ Decision

Decision Date
# IFNγ Cohort Submission

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## TB Skin Readings

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<td>B</td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

**V.I. Signature:** ..................................................  **Date Posted:** ..................................
APPENDIX 4

AHCS - Contiguous and Special Programmes

Contiguous and special testing programmes may be created on AHCS for TB. **A herd may be included in more than one testing programme (e.g. if it is contiguous to two or more TB index herds) but it will only be tested in one programme at a time.**

If at the time of creation of a programme, the system finds that a herd is part of an existing programme, the herd can be added to the new programme but will continue to be tested in the existing programme. It will be flagged as “Not Tested in this Programme” in the new programme i.e. **test column will have an “N” present.**

When the herd’s current testing programme finishes, the herd will then be tested as part of whatever other programme(s) it is included in until such time as all of the programmes have ended. If it is part of more than one other programme, the system will make it active in whichever programme has started most recently and has the highest risk level. If the herd is not present in other programs, the herd will be listed for a Round Test twelve months from the date of last herd level test.

Similarly, in some cases, the equivalent test rules will mean that a new test will not be created in a programme if a herd is scheduled for a test with a higher priority. However, when the latter test is followed up the system will prompt for a test in the programme created (if the test is clear). If a herd in a programme should itself breakdown, it will remain as part of the programme **but will go through the normal reactor re-test lifecycle.** When the herd goes clear and if the programme has not ended, it will be scheduled for a test in the programme if programme test has higher priority.

**Monitoring**

V.I.s should actively monitor and manage the contiguous programmes in their areas of responsibility and regularly review the herds to be listed for contiguous tests including any that should be added to a programme e.g. when an outbreak continues and reactors are no longer confined to the original location and/or animals have been housed/grazed since the programme was established. In cases where there is deviation from policy there should be a record on the herd file as to the decision of the V.I.
APPENDIX 5

Procedures for Back trace reactor/Lesion in exported animal

Step 1 Create the PM test. (Admin function)
Create PM test
Enter tag no. and accept the default test description and type
Select Retrieve

[Note: Herd Number will show the last herd the animal was in pre export. Factory Code will show the export location]

The PM test is now created at a status of Awaiting Results

Step 2.
TB Post mortem result entry (Admin function)
- Enter Factory code F999 for NI  F998 for all other destinations (eg GB)
- Test date as on HQ email
- Kill no. 999
- Lesion – as on email  e.g bronchial etc
- Press Complete

Follow-up the PM test – there will now be a TB tissue test at a status of Awaiting samples
Step 3 Record a General Comment (Admin function)
1. Record a General Comment against the TB tissue test (e.g. lesion at PM in NI) and tick the Display at Interpretation tick box.

Step 4 Enter results on the TB Tissue test (VI function)
1. Check the No sample Received check box and record a VI comment.
Select Submit
The Tissue test is updated to Awaiting Interpretation.
DO NOT INTERPRET THE TISSUE TEST UNTIL RESULTS HAVE BEEN NOTIFIED BY HQ.
Step 5 Interpretation of the Tissue Test (VI function)

Record an overall result as appropriate e.g. Positive and update the VI comment
Select Interpret
Follow-up the TB tissue test
APPENDIX 6

SINGLETON TUBERCULIN TEST REACTOR PROGRAMME

1. All index tests which reveal single reactors will be reviewed at the start of each week to assess the number of potential candidate herds/animals that will require separate identification for segregation and subsequent handling at the factory.
2. To facilitate this review it will be necessary to know the readings for these animals. Where reports are not yet to hand the testing veterinarians must be contacted.
3. An ER26S permit should be used in respect of candidate animals.

Procedure at the Factory

1. Singleton reactors for special post-mortem examination will be identified by green coloured spray and highlighted on the singleton reactor movement permit (ER 26S).
2. These cattle should be kept separate and slaughtered as a group.
3. The line should be slowed down to allow adequate time for slicing of glands removal and identification of samples and sterilisation of knives between each animal.
4. If lesions typical of tuberculosis are detected samples need not be taken for laboratory examination.
5. If lesions are not detected then the retropharyngeal, submaxillary, parotid, bronchial and mediastinal lymph nodes should be collected for laboratory examination. The head and thoracic glands should be put into separate pathoseal bags.
6. The Veterinary Inspector responsible for the factory should supervise the slicing and collection of lymph nodes to ensure that knives are sterilised between each sample. It is most important that cross contamination is avoided between samples.
7. The pattern of isolates from NVL lymph nodes will be monitored as a quality control measure to check for cross contamination. CVRL staff may also visit factories during sampling to assess quality control factors.

Procedure for Packing and Identification of Samples from Singleton Tuberculin Test Reactors

Note: When creating the ER47 the drop down box on screen will prompt the permit type which should be input as ER26S Singleton and not Slaughter Check.

1. The tag number should be written on the pathoseal bags containing the samples.
2. Samples from each animal should be placed in a separate pathoseal bag. Each bag must contain glands from only one animal and be accompanied by a copy of the ER47 placed in the pouch of the pathoseal bag.
3. A green label (to be issued) identifying the sample as from a singleton reactor should be put on the outside of bag.
4. A matching green label should be attached to the lower right hand side of the ER47 form accompanying the samples. A separate ER47 form should be completed for each animal and attached to the outside of the pathoseal bag.

Laboratory Examination

All samples will undergo further slicing in the laboratory to detect any lesions that may be missed at the factory. A sample of any lesions detected will be prepared for histopathological examination. Where specific non tuberculous lesions are identified culturing of the remaining tissues will be undertaken.

Tuberculous lesions will be identified on histological examination where the presence of a granulomatous lymphadenitis (Langhans Giant cells and Epitheliod cells) associated with caseous necrosis are observed. No further culturing will be undertaken in these circumstances.

If visible lesions are not detected a sub-sample of the glands submitted will be prepared for cultural examination.

Cultural examination will consist of the BACTEC method plus the inoculation of two tubes of Lowenstein Jensen medium.

Presumptive identification of isolates will be based on growth characteristics, appearance of the isolate, detection of cording and sensitivity to para nitrobenzoic acid. A proportion of the isolates will be subjected to DNA probe and/or biochemical testing as a quality control measure.

Cultures will be deemed negative if growth is not detected after 7 weeks.

An email will be sent to the DVO via AHCS when final results (based on histopathological and or cultural examination) are available.

Progress of details of samples and results may be tracked on AHCS.
APPENDIX 7
Inconclusive Reactors

Decision Chart for TB inconclusive reactors relating to amended 64/432/EEC

Report with Inconclusive reactors received at DVO |

<table>
<thead>
<tr>
<th>VI interprets test</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. If the herd has had its trading status withdrawn within the last three years then A.</td>
</tr>
<tr>
<td>(or)</td>
</tr>
<tr>
<td>Animal bought in and history indicates exposure then A</td>
</tr>
<tr>
<td>(or)</td>
</tr>
<tr>
<td>Lesioned animals traced to this herd then A</td>
</tr>
<tr>
<td>(or)</td>
</tr>
<tr>
<td>Contiguous herds experiencing H class breakdown then A</td>
</tr>
<tr>
<td>(or)</td>
</tr>
<tr>
<td>VI decision that infection is probable then A</td>
</tr>
<tr>
<td>(or)</td>
</tr>
<tr>
<td>Deem I/R to be 'reactor' then treat as normal reactor herd.</td>
</tr>
<tr>
<td>2. If herd not any of above then B.</td>
</tr>
</tbody>
</table>

A |

| Herd must be restricted (ER22 by post). |
| Letter to Herdowner |
| All ID documents returned to DVO |
| Letter to PVP. |

B |

| Inconclusive reactor(s) ID document(s) returned to DVO. |
| Letter to PVP instructing that rest of ID documents can be returned to herdowner but animals not eligible for intra community trade i.e. no export certs. to be issued for that herd. |

When A or B occurs restoration of herd's clear status can be by

(i) Inconclusive reactor retested after 42 days and passes test.

(ii) Inconclusive reactor sent to factory and glands cultured and negative

(iii) Inconclusive reactor not available for TB test then clear herd test 42 days after Inconclusive reactor leaves herd

(iv) Inconclusive reactors glands not tested then clear herd test 42 days after Inconclusive reactor leaves herd

Synopsis of Farmer decision with TB Inconclusive reactors in his/her herd.

Inconclusive reactor disclosed at any test. What can you do to regain clear herd status and be free to trade again.

Send Inconclusive reactor to factory and when NVL get a Department paid test in 42 days. (only if you have already paid for a test this year/or in the previous10 months)

Send Inconclusive reactor to factory and get glands cultured. Culture must be negative and takes 8 weeks to process

Retest Inconclusive reactor after 42 days and hope it passes the test

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APPENDIX 8

ATYPICAL HERDS

The Selection and management of NVL - Reactor herds.

THE SELECTION AND MANAGEMENT OF A GROUP OF RECURRING NO VISIBLE LESIONS (NVL) REACTOR HERDS.

ONE DISTRICT VETERINARY OFFICE’S (DVO) EXPERIENCE.

John Murray and J McCarthy

Definition

The vast majority of Tb reactor herds behave in a typical manner and are progressed through their restriction to clear status without raising further questions. However, within the restricted herd population there is a subset of herds that behave in an atypical manner in that:

- They produce unusually large numbers of no visible lesion (NVL) reactors.
- They experience repeat ‘reactor’ episodes.

These restricted herds pose a challenging management problem. A serious doubt exists as to their true disease status that is not easily resolved.

Background

Table A lists 5 such herds in which investigations commenced in 1996 and proceeded onwards. Experience with these herds suggested that their reactors were not all due to infection with Tb. There was prima fascia evidence in one case of interference with the mammalian test site. The evidence was less obvious but no less convincing in other cases being based more on herd history, post mortem results and the type of reactor being disclosed. In these 5 herds the evidence was never sufficiently robust to define a prosecution for interference with a test under the animal health legislation and thus no case was ever taken before the courts.

From 1990 to 1999 these 5 herds produced large numbers of NVL tuberculin test reactors that were reported to the District Veterinary Office (DVO) already tagged and punched by the Private Veterinary Practitioner (PVP). From 1996 onwards the approach taken was to suspend the collection of the reactors pending further investigation. These investigations involved examining the reactors on farm, interviewing the clients, interviewing the PVP, taking blood samples, being present at the slaughter of the reactors, taking gland samples for culture while trying to maintain good relations with the unhappy client throughout the investigation. Ultimately, where the evidence was strong enough, grant payments were refused and this always led to protracted disputes.

This approach proved very difficult to sustain as herdowners wanted immediate explanations for their continuing restrictions. They wanted their reactors removed, grants paid and the herd derestricted. They were not impressed with the investigations. Representations were made through the Farmer representative organisations, Department of Agriculture headquarters, Legal representatives, Local Authority representatives, Politicians also made representations at every level and ultimately the ombudsman’s opinion was sought.

It became clear that this approach was too difficult to sustain in a busy DVO. Legislation hampered the rational veterinary decision making process. The key obstruction was that once an animal was deemed to be a reactor by a veterinary surgeon and was tagged and punched, that its status could not be reversed.

Modified approach

The solution to the problems experienced was to devise a letter of instruction to the nominated PVP, advising him/her, amongst other things, of the herd history and instructing him/her to conduct the test as normal but not to tag and punch any animals with positive reactor measurements. The PVP was instructed to leave all interpretations to the DVO. He was also requested to advise the client of the change of procedure. A sample copy of this letter is attached (Appendix i). It was well received by the PVPs.

The effect of the letter was rationalised as follows:

If a herdowner was interfering with a test, clearly he would cease to do so having been advised by his PVP of the letters contents. The letter should therefore separate real problems, such as Tb and non-specific-infection (NSI), from contrived problems such as test interference. There was no basis for arguing against the letter or the policy behind it. It offered a very friendly management approach to the DVO, the herdowner and the PVP, for dealing with these difficult cases.
The methodology for dealing with any reactors arising was decided based on earlier experience gleaned from dealings with the herds in Table A. The approach was to be as follows:

Reactors were to be notified immediately by telephone, as per instructions, to the Superintending Veterinary Inspector (SVI). They were not to be tagged and punched as reactors.

An immediate appointment was to be made with the herdsman for the assembly of the reactors for inspection by the nominated Veterinary Inspector (V.I.).

The herd was to be restricted and the reactors segregated as normal pending resolution of the problem.

All reactors disclosed were to be examined. A lot of time and resources had been invested in setting up the exercise. Therefore, it was important that there was a clear intent to follow up every case.

Discussions with the herdsman were to be non-confrontational and matter of fact.

Each reactor was to be examined to evaluate the sites of injection and to form a judgement as to whether the sites were normal.

Each reactor was to be examined to evaluate its status within the herd. Did the reactors represent a serious economic loss to the herdsman? Cases had come to light where over a number of years no culs were removed other than as reactors.

Blood samples were to be taken for ELISA Testing and/or Gamma Interferon Testing.

Based on observations a decision would be made whether to slaughter or hold the reactors.

If reactors were held they would be re-examined to see how the skin injection sites were progressing. It has been observed that where foreign substances are used for the manufacture of false reactors the skin lesions may progress in a manner quite unlike Tb type reactions.

Based on observations animals might be followed to the factory where skin and gland samples would be taken for analysis.

The opinion of the PVP who attended the herd would be sought.

In cases where reactors were to be held for long periods and where supporting tests indicated that the SICT had not provided an accurate assessment of the true disease status of the herd and the reactors, the SICT was to be repeated after an appropriate interval.

Because the animals would not have been presented tagged and punched as reactors a decision would ultimately have to be made by the SVI as to the disease status of the animals and of the herd. This would be done in consultation with H.Q.

From 1999 onwards this letter was sent to the PVP with all test notifications for the 5 herds in Table A. It seemed from an early stage that the letter had an effect on the disclosure of reactors in this particular group of herds. Up to the 31 Dec’2001 no further reactors were disclosed in these 5 herds. A very useful tool to deal with the Recurring NVL Reactor Herd had been discovered.

At the end of 1999 the apparent success of the exercise was so encouraging that the sample was expanded. Thus a list of 46 herds was drawn up at the beginning of 2000. The criteria used in selecting the sample were as follows:

1. All herds on the reactor register categorised at high risk of further Tb-breakdown were examined and those with recurring NVL reactors or other suspect features were selected.
2. Herds with substantial long-standing income supplement payments were likewise examined and selected if they fitted the criteria.

From the herds within the above 2 groups 41 herds were selected and were added to the original sample. The vast majority of these herds were selected purely from their records and were otherwise unknown. Once the selection was made no further herds were added to the list. Other herds that came to notice after the original selection were dealt with separately. It cannot therefore be argued that the outcome of this exercise was influenced by retrospective additions of information that fitted the emerging picture.

Methodology

A special PVP code was created for these 46 herds so that when they fell due for a Tb test the test listing was given initially to the SVI. No targeted test scheduling of these herds took place. The only change of procedure was that the standard letter, adapted for each herd as it fell due for test, was sent by the SVI to the nominated PVP for the herd. It was intended to investigate all animals subsequently reported as having readings indicating failure of the tuberculin test. This task of examining, at short notice, all the reactors disclosed would stretch resources. As events unfolded however, the number of reactors fell from 522 in 1999 to 66 in 2000 and 26 in 2001 at 31/12/01 and therefore the problem was much less than expected.

From February 2000 every herd test undertaken on the herds within the selected group was conducted under this protocol. In excess of 150 letters were written by the SVI each one tailored to the particular case. All the reactors notified were brought to the SVI’s attention. The farm was then visited and the reactors inspected. The outcome of this exercise is summarised, in its historical perspective, in the Tables below.
Tables of Results
The results tables were constructed as follows:
1. Each herd was assigned a number, which is referenced to its herd number.
2. The average herd size is deduced for an 11-year period.
3. The review was conducted from 1990 to 2001 inclusive.
4. “Number of episodes” refers to the cumulative number of reactor tests with the disclosure of one or more reactors at each test since 1990.
5. The finding of single or multiple lesions per episode received a value of 1 and this total is expressed as “Episodes + Lesion”.
6. The total number of reactors for the period 1990 to 2001 inclusive is given under “No. of Reactors to 2001”.
7. The number of animals with a lesion is shown as “Reactors + Lesion”.
8. The “Year of Last Reactors” gives the year in which reactors were last disclosed prior to 2000.
9. “Current status” should be interpreted as “Rnd’02”=clear and returned to round 2002; “SMCT,02”=SMCT due in 2002; “Ct’02”=Contiguous test due in 2002; “RR’02”=Reactor retest due in 2002.

Findings:
No further reactors were disclosed in the 5 original herds (Table A) after the letter was first used in 1999.

Table A.
Initial 5 herds where investigation commenced in 1996 and letter issued from 1999

<table>
<thead>
<tr>
<th>No</th>
<th>Herd Size</th>
<th>No. of Episodes</th>
<th>Episodes + Lesion</th>
<th>No. of Reactors to 2001</th>
<th>Reactors + Lesion</th>
<th>Year of last Rs</th>
<th>Current status</th>
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<td>0</td>
<td>25</td>
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<tr>
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<td>9</td>
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<td>61</td>
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<td>3</td>
<td>139</td>
<td>3</td>
<td>1998</td>
<td>Rnd’02</td>
</tr>
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</table>

No further reactors were disclosed in a group of 23 herds (Table B) after the letter was first used from February 2000.

Table B.
23 herds from the selection of 46 where no reactors were disclosed following initial use of “the letter” in February 2000.

<table>
<thead>
<tr>
<th>No</th>
<th>Herd Size</th>
<th>No. of Episodes</th>
<th>Episodes + Lesion</th>
<th>No. of Reactors to 2001</th>
<th>Reactors + Lesion</th>
<th>Year of last Rs</th>
<th>Current status</th>
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<td>1</td>
<td>39</td>
<td>1</td>
<td>1997</td>
<td>Rnd’01</td>
</tr>
</tbody>
</table>
Reactors were disclosed in 14 herds after the letter was first used from February 2000, albeit in much reduced numbers (Table C). These animals were all investigated by the area V.I. and the SVI and decisions made as to their status. The reactors disclosed in these herds and their lesion status for 2000 and 2001 is summarised in the last four columns of Table C.

Table C:
14 herds from the selection of 46 where reduced numbers of Reactors were disclosed following initial use of ‘the letter’ in February 2000.

<table>
<thead>
<tr>
<th>No</th>
<th>Herd Size</th>
<th>No. of Episodes</th>
<th>Episodes + Lesion</th>
<th>No. of Reactor to 2001</th>
<th>Reactor + Lesion</th>
<th>Year last reactors</th>
<th>Reactors 2000</th>
<th>Reactors 2000 + Lesion</th>
<th>Reactors 2001</th>
<th>Reactors 2001 + Lesion</th>
<th>Current Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>33</td>
<td>60</td>
<td>6</td>
<td>3</td>
<td>53</td>
<td>4</td>
<td>1999</td>
<td>0</td>
<td>0</td>
<td>20</td>
<td>6</td>
<td>SMC’02D</td>
</tr>
<tr>
<td>34</td>
<td>130</td>
<td>2</td>
<td>0</td>
<td>19</td>
<td>0</td>
<td>1998</td>
<td>8</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>Rnd’02</td>
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<tr>
<td>35</td>
<td>220</td>
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<td>5</td>
<td>78</td>
<td>5</td>
<td>1999</td>
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<td>0</td>
<td>0</td>
<td>Rnd’02</td>
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<tr>
<td>36</td>
<td>100</td>
<td>11</td>
<td>2</td>
<td>63</td>
<td>7</td>
<td>1999</td>
<td>5</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>Rnd’02</td>
</tr>
<tr>
<td>37</td>
<td>250</td>
<td>15</td>
<td>5</td>
<td>96</td>
<td>9</td>
<td>1998</td>
<td>6</td>
<td>2</td>
<td>3</td>
<td>0</td>
<td>SMC’02</td>
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<tr>
<td>38</td>
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<td>1</td>
<td>28</td>
<td>1</td>
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<td>1</td>
<td>0</td>
<td>0</td>
<td>Rnd’02</td>
</tr>
<tr>
<td>39</td>
<td>190</td>
<td>12</td>
<td>0</td>
<td>42</td>
<td>0</td>
<td>1999</td>
<td>6</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>Rnd’02</td>
</tr>
<tr>
<td>40</td>
<td>160</td>
<td>15</td>
<td>3</td>
<td>82</td>
<td>3</td>
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</tr>
<tr>
<td>41</td>
<td>200</td>
<td>8</td>
<td>4</td>
<td>50</td>
<td>8</td>
<td>1999</td>
<td>4</td>
<td>1</td>
<td>2</td>
<td>0</td>
<td>SMC’02</td>
</tr>
<tr>
<td>42</td>
<td>40</td>
<td>6</td>
<td>1</td>
<td>14</td>
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<td>1999</td>
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</tr>
<tr>
<td>43</td>
<td>120</td>
<td>7</td>
<td>4</td>
<td>30</td>
<td>4</td>
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<td>5</td>
<td>2</td>
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<td>0</td>
<td>SMC’01</td>
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<td>46</td>
<td>5</td>
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<td>0</td>
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</tr>
<tr>
<td>45</td>
<td>130</td>
<td>4</td>
<td>1</td>
<td>33</td>
<td>3</td>
<td>1999</td>
<td>6</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>SMC’02</td>
</tr>
<tr>
<td>46</td>
<td>160</td>
<td>8</td>
<td>5</td>
<td>39</td>
<td>12</td>
<td>1999</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>Rnd’02</td>
</tr>
</tbody>
</table>

No. 33 is worthy of special comment. This herd disclosed a factory lesion and was manually listed for an immediate test to the nominated PVP. The factory lesion retest (FLR) did not alert the system of notification. No letter was ever sent. The test produced 14 reactors with 6 lesions. More reactors were disclosed at subsequent tests and the herd was depopulated. Clearly the failure to send the letter in this case had no bearing on the outcome.

No 45 also disclosed a factory lesion and escaped the letter for the test that recorded 6 reactor cows in 2000. Attention was not drawn to these animals and all were NVL.

In the course of this exercise two herdowners who were not part of the original selection but whose herds had fitted the same criteria, were suspected of interfering with their Tb tests (Table D). Their cases were investigated with the help of the Department of Agriculture’s Special Investigation Unit and the Gardai. They were brought before the courts where they pleaded guilty to charges of fraud and cruelty by interfering with tuberculin injection sites for the manufacture of false reactors. The letter protocol was not put in place in the case of these herdowners until after they were prosecuted.

Table D:
Two herds not part of the original selection of 46 against whom legal proceedings were taken.

<table>
<thead>
<tr>
<th>No</th>
<th>Herd Size</th>
<th>No. of Episodes</th>
<th>Episodes + Lesion</th>
<th>No. of Reactors to 2001</th>
<th>Reactors + Lesion</th>
<th>Year of last Rs</th>
<th>Current Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>47</td>
<td>160</td>
<td>5</td>
<td>1</td>
<td>43</td>
<td>2</td>
<td>1999</td>
<td>Rnd’02</td>
</tr>
<tr>
<td>48</td>
<td>155</td>
<td>8</td>
<td>2</td>
<td>46</td>
<td>3</td>
<td>1999</td>
<td>Rnd’02</td>
</tr>
</tbody>
</table>

The lesion rate in the reactors was uncomfortably low for ‘97, ‘98, and ‘99. It rose to 7% and 24% in 2000 and 2001 (Table E).

Table E:
Lesion % Rate for Cows and Heifers

<table>
<thead>
<tr>
<th></th>
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<th></th>
<th></th>
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<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>12.5</td>
<td>26</td>
<td>11.5</td>
<td>7.5</td>
<td>5.4</td>
<td>2</td>
<td>8.7</td>
<td>6.2</td>
<td>4.3</td>
<td>5.8</td>
<td>7</td>
<td>24</td>
</tr>
</tbody>
</table>

The reactor population in these herds was greatly reduced in 2000 and 2001 (Table F). The visible lesion rate in 2000 remained very low (Table G). All the lesions disclosed in 2001 occurred in one herd i.e. Herd no 33.
Table F.
Reactor population in the 46 selected herds.

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
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<tbody>
<tr>
<td>cows</td>
<td>82</td>
<td>16</td>
<td>59</td>
<td>98</td>
<td>77</td>
<td>82</td>
<td>170</td>
<td>217</td>
<td>364</td>
<td>383</td>
<td>37</td>
<td>18</td>
<td>1603</td>
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<tr>
<td>heifers</td>
<td>22</td>
<td>6</td>
<td>10</td>
<td>35</td>
<td>34</td>
<td>77</td>
<td>82</td>
<td>11</td>
<td>4</td>
<td>369</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>steers</td>
<td>10</td>
<td>9</td>
<td>6</td>
<td>7</td>
<td>4</td>
<td>4</td>
<td>30</td>
<td>39</td>
<td>45</td>
<td>37</td>
<td>16</td>
<td>3</td>
<td>210</td>
</tr>
<tr>
<td>calves</td>
<td>1</td>
<td>1</td>
<td>2</td>
<td>1</td>
<td>1</td>
<td>4</td>
<td>12</td>
<td>1</td>
<td>8</td>
<td>8</td>
<td>1</td>
<td>1</td>
<td>23</td>
</tr>
<tr>
<td>bulls</td>
<td>1</td>
<td>3</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>4</td>
<td>8</td>
<td>8</td>
<td>1</td>
<td>1</td>
<td></td>
<td></td>
<td>35</td>
</tr>
</tbody>
</table>

Table G.
Visible Lesions in the 46 selected herds

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
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<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>cows</td>
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<td>3</td>
<td>6</td>
<td>7</td>
<td>4</td>
<td>2</td>
<td>13</td>
<td>8</td>
<td>12</td>
<td>25</td>
<td>2</td>
<td>5</td>
<td>99</td>
</tr>
<tr>
<td>heifers</td>
<td>1</td>
<td>2</td>
<td>2</td>
<td>3</td>
<td>2</td>
<td>5</td>
<td>8</td>
<td>7</td>
<td>2</td>
<td>2</td>
<td>1</td>
<td></td>
<td>35</td>
</tr>
<tr>
<td>steers</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>5</td>
<td>19</td>
<td>6</td>
<td>6</td>
<td>4</td>
<td></td>
<td></td>
<td></td>
<td>50</td>
</tr>
<tr>
<td>calves</td>
<td></td>
<td>2</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>3</td>
</tr>
<tr>
<td>bulls</td>
<td>1</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>3</td>
</tr>
</tbody>
</table>

Few reactors were disclosed, within the selected sample, during the course of the exercise. Therefore no significant number of reactors required investigation.

Discussion

The phenomenon of recurring NVL reactor herds, with few exceptions, was geographically confined to the mid-west of the DVO being confined to the hinterlands of 4 regional towns. This area has had a very high APT (Animals Reactor per Thousand Animal Tests) for the last 5 years. Consequently the exercise was confined to a few veterinary practices, one practice having 15 of the herds listed.

Reference is made to the cow and heifer reactors only in the 2 graphs. This combination formed the majority of reactors and these reactors command the higher grant compensation rate especially pregnant heifers.

The downturn in reactor numbers, after the circulation of the letter was sudden and unexpected. This raises a number of questions.

Why did the reactor numbers decrease so dramatically? Was it co-incidentally a natural event in the cycle of the recurring NVL reactor phenomenon or was the letter substantially responsible for the massive drop in the reactor population in these herds after 1999? It is worthy of note that this group of herds produced more than 10% of all the reactors in the DVO in 1997, 1998 and 1999.

Would the same result have been seen with a greatly expanded sample or if the qualifying criteria had been less selective?

These questions can be answered only by enlarging the sample and repeating the exercise in other V.I. areas or even nationally. The approach taken was likely responsible for at least part of the decrease in reactor numbers. The cases of the two herdowners in Table D illustrate this point. It is certain that the disclosure of false reactors in these cases would have ceased had they been part of the protocol. The letter and its implied follow up procedures is therefore a very useful management tool where test interference is suspected. It could perhaps be further enhanced. It should not however be used to provide an escape route for people who have broken the law and against whom a case of fraud can be prosecuted.

Summary:

This exercise was originally conducted for the purpose of formulating an approach to the vexatious problem of the persistent repeat NVL reactor herd. It had a surprising and unexpected outcome in that the phenomenon immediately disappeared both in the initially small and later expanded selected sample. This selection of problem reactor herds has been dealt with successfully in a cost effective manner. No short cuts were taken in any case. Few reactors were disclosed and all herds except No 3, which awaits its clearance test after the disclosure of a factory lesion, have clear status.

The entire operation was very time consuming. It was run on a day-to-day basis by the SVI and one designated V.I. Consideration should be given to the possibility of establishing such an exercise as part of the normal Tb eradication programme with administrative backup and with defined protocols to be followed in cases where reactors are disclosed.
Veterinary Practitioner  
Co.  

Re: Round TB Test of John Farmer, XXXXXXXXX, Co..  
Herd No. 123456x?  
Herd size. 50 animals . 20 cows.  

Dear colleague,  

I refer to the TB test currently listed to your practice for the above herd. As you are aware we have encountered great difficulty in resolving a reactor problem which has recurred in this herd since 1996. Since the test of 17/10/96 thirty nine reactors have been disclosed. 29 cows, 7 heifers, 1 bull and 2 calves have been removed as reactors. Only one of these showed lesions on post mortem and this was an unconfirmed prescapular lesion. This was as far back as 1998.  

In order to progress this investigation further I require that you advise me in advance of the date and time of the injection of the herd with tuberculin. In the event of any animals with positive mammalian reactions arising at the reading of this test I require that this office be informed immediately by telephone of that fact and a copy of the test report forwarded to me at the DVO for interpretation. Please record all measurements and leave the interpretation of this test entirely to the DVO i.e, no animals are to be tagged and punched as reactors.  

I would appreciate it if you would make your client aware of this investigation in advance of the test so that he will not be surprised by the changed procedures should reactors arise.  

Your personal observations and recommendations will of course be appreciated.  

Yours sincerely  

______________  S.V.I.
To: -  
XXXXXXXXX MRCVS
XXXXX,  
Co. Cork

Re: R/R Test XXXXXXXXX, Co. Cork.  
Herd No. XXXXXXXX D  
Herd size. 100 animals .   Test due: XX/XX/20XX

Dear colleague,

I refer to the R/R Tb test currently listed to your practice for the above herd. As you are aware we have encountered great difficulty in resolving a reactor problem, which has recurred in this herd since 1997. Furthermore, a review of this herd’s Tb file suggests that severe interpretation is inappropriate to this herd at this time. The record is as follows since 1997:

<table>
<thead>
<tr>
<th>Year</th>
<th>No. of episodes</th>
<th>No. of episodes with lesions</th>
<th>No. of reactors</th>
<th>No. of reactors with lesions</th>
<th>Lesion rate %</th>
<th>Expected Lesion rate % in Standard reactors</th>
</tr>
</thead>
<tbody>
<tr>
<td>1997</td>
<td>2</td>
<td>2</td>
<td>12</td>
<td>4</td>
<td>25</td>
<td>35</td>
</tr>
<tr>
<td>1998</td>
<td>2</td>
<td>1</td>
<td>14</td>
<td>1</td>
<td>7</td>
<td>35</td>
</tr>
<tr>
<td>1999</td>
<td>1</td>
<td>0</td>
<td>12</td>
<td>0</td>
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<td>35</td>
</tr>
<tr>
<td>2000</td>
<td>3</td>
<td>0</td>
<td>25</td>
<td>0</td>
<td>0</td>
<td>35</td>
</tr>
<tr>
<td>2001</td>
<td>2</td>
<td>2</td>
<td>21</td>
<td>2</td>
<td>9</td>
<td>35</td>
</tr>
<tr>
<td>2002</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The department would like to investigate this type of case should reactors arise at the next test. In order to progress this investigation further I require that you advise me, in advance of the date and time of the injection of the herd with tuberculin. In the event of any animals with positive mammalian reactions arising at the reading of this test, I require that this office be informed immediately by telephone of that fact and a copy of the test report forwarded to me at the DVO for interpretation. Please record all measurements and leave the interpretation of this test entirely to the DVO i.e. no animals are to be tagged and punched as reactors.

The DVO will decide on the basis of post mortem findings or other supplementary tests what animals will be removed and we will advise you accordingly. I would appreciate it if you would make your Client aware of this investigation in advance of the test so that he will not be surprised by the changed procedures should reactors arise.

Your personal observations and recommendations will of course be appreciated.

Yours sincerely

______________  S.V.I.
ATYPICAL HERDS - RVO PROCEDURE

Mr. Martin Blake DCVO
Ms. M. Good SSVI
Mr. J. Murphy AP

RE: Management of herds designated as having a history of an Atypical TB breakdown(s).

As requested I have looked at the various possibilities of managing these herds as a group within the DVO. The various options for identifying and tracking herds included the following

(i) a Herd Category other than A,B,C or D
(ii) a Blackspot Letter not in use
(iii) A distinct PVP code

In making the final decision, it must be kept in mind that when the test is listed and the listing is printed, it must ring a bell immediately that this listing is to be accompanied by the ‘atypical’ letter to the PVP.

If the means of identifying the herds was Herd Category or Blackspot, then it is entirely possible that a listing could issue to a PVP without anybody realising that it was an ‘atypical’ herd. Therefore from this perspective alone, a unique PVP code seemed the best option.

From the point of view of analysis of reports (stats and herd test histories) the unique PVP code offers the same flexibility as any other means of identification. It is possible to get a stat based on a PVP code. The herd test histories can be printed (six at a time) using the individual herdnumbers. It is also feasible to write a report in Report Generator giving summary information on herds with a certain PVP code.

From an ERAD management perspective, it would make more sense to use a specific PVP code for use in all DVO’s (rather than using SVI codes). This, I presume, would enable ERAD HQ to print summary reports and the TIU to analyse data.

I suggest a code such as 2020 this code has never been issued (relates to a qualification in 1920). I suggest we call this vet Murray McCarthy in honour of the men who pioneered the system.

The herdfiles should be identified/highlighted so that the interpreting VI is alerted to the fact that this herd is an ‘atypical herd’. A sticker could be placed on the file with the following inscription **Atypical Herd Vet Code 2020.**

The listing of the herd/s would operate as follows:

The listing would print off in the normal way to Vet 2020.

The first page of the listing (containing the name of the vet) would be discarded and the second page (which is the actual listing) could be attached to the ‘Murray’ letter and sent to the PVP. [It is possible to single-schedule the test to the PVP on the computer and then print off a listing but I don’t think it is worth the trouble]

Notes of caution

1. Make a record of the existing PVP on the file before changing it to 2020.
2. Each DVO should check the list of herds that were handed out at the last regional meeting before ‘treating’ them to this regime. In some cases the presence of lesions post-mortem may not have been accurately recorded on the computer and they do not in fact fit the high NVL rate criteria set.

Summary for DVO

1. Check the list supplied from HQ and eliminate those herds where the lesion rate is in fact normal (notify TIU of eliminations and details).
2. On computer, change the **attendant PVP and schedule vet** to 2020
   ➢ Prepare the ‘Murray’ letter to issue to the PVP.
   This can either be a standard template letter, which is filled-in appropriately at the time of the listing, or, a letter written as a Mail Merge Document and merged to a table of data.

Patrick Flanagan SSVI
ATYPICAL HERDS - ON-FARM PROCEDURE

STEPS TO FOLLOW WHEN A HERD ON THE ATYPICAL LIST SHOWS 'TB REACTOR' SICCT READINGS.

As far as possible these herds should be treated in a standard manner. Given their history a potential NSI problem must be suspect and severe interpretation, as a routine, should be withdrawn to avoid unnecessary decimation of the herd.

At each stage any observations should be recorded (contemporaneous notes):

(i) Visit the herds on the day of reading or as soon as possible thereafter;
(ii) Check the animal(s) and record salient details such as body/udder condition, presence of scour (query Johne’s disease), skin TB etc.;
(iii) Query any pertinent husbandry details e.g. is poultry manure fed;
(iv) Examine the injection sites - these should be normal in appearance and texture with no abnormalities evident (if an aromatic substance such as turpentine or diesel is used to interfere the smell may be detectable on fingers following palpation of the lump) and if later than the reading day, lump measurement should show the normal post 72-hrs 'waning' response - record measurements and observations;
(v) Examine both the tags and the ears. If a suspicion is formed that tags may have been switched then remove the tags and submit for examination maintaining chain of evidence procedures; Please note that it appears that the latest way to switch a tag is using a sharp knife make a small slit out from the tag-hole, roll up the tag and feed it through the slit, the tag remains undamaged and the slit heals naturally. If this is suspected then a blood sample should be taken for DNA analysis and comparison with 'blood relatives' (dam/offspring/siblings). The reactor in question may well be genuine and will have to be removed from the herd in any event in which case the ear should be taken for laboratory examination (presence of scar/healing wound).
(vi) Return to farm day 10 (or later) following the injection of tuberculin to take blood samples and submit for standard interferon γ assay and additionally request ESAT6 interferon γ assay.

When results of Gamma interferon tests are to hand there are three possible directions.

1. The Gamma interferon test results correlate (~80% correlation is usual) and the decision is made to deem the animal(s) reactor and remove as normal. Reactors from these NSI herds should be treated as per the 'singleton' regime. This will serve two purposes (i) allow data analysis to determine if there is a particular type of interferon-γ assay NSI-type response and (ii) provide an adequate database on which to base future decisions on the herd in question.

2. The Gamma interferon test results do not correlate.
   a. If test interference at the injection site is evident e.g. larger lump, abscess formation, adherence to underlying tissue etc. the Gardaí should be alerted to a suspect fraud, and the animals should remain for retest.
   b. If test interference at the injection site is not evident or is unclear then it may be desirable to have skin sites taken at p.m. for analysis (Abbotstown requests that both avian and bovine sites should be submitted for response comparison) and glands should be taken for full laboratory examination. Full chain of evidence protocols should be rigorously followed. Reactor payment section should be notified that payments should not be made until the situation has been clarified.

3. The Gamma interferon test results show poor correlation.
   In such cases the procedure outlined in two above should be followed bearing in mind that there may be other factors superimposed on a genuine TB problem.

At any stage where the situation is unclear the Regional SSVI should be consulted for guidance.
APPENDIX 9

Scientific Papers

Paper 1.

Incidence and Prevalence.

Margaret Good

Department of Agriculture, Food and Rural Development, Agriculture Hse., Kildare St., Dublin 2. Ireland.

The terms incidence and prevalence are often used incorrectly and sometimes even interchangeably in the same article. Hence, I have tried to provide a guideline as to their meanings below that I hope may prove helpful.

**Incidence** is a dynamic measure of disease occurrence. It describes the probability of a new case developing during a specified time interval. Thus by definition, incidence rates require a minimum of two sets of measurements or tests: – one at the start of the period of observation to ensure that the animals did not have the disease, condition or infestation and the second sometime later to investigate if the disease developed during the intervening period. The period must always be stated when reporting results because the rate may change with time, from season to season or year to year. A basic rule is that one herd can only experience the event once during the study period. Thus, if multiple observations are made (i.e. more than 2) the average number of herds at risk over the study period must either be calculated or estimated. An estimate of the approximate number of herds at risk (NAR) could be taken as the number at risk initially added to the number at risk at the end of the period divided by 2. Rates may be reported for time intervals that are sub-sections of the full study period as when individual monthly rates are calculated from a 12 month study. The general formula for incidence is the number of herds developing disease during the time period divided by the average herds at risk taking into account the time component being quoted. Thus the incidence of TB in herds over say a study period of one month would be:

\[
\frac{\text{Number of new herd breakdowns during a month}}{\text{Number of herds tested during that month (NAR)}}
\]

Herds which experience breakdowns during the month should not be included as at risk at the end of the month even if they are disease free. If detailed records are available the exact denominator could be calculated but generally such accuracy is not required and the NAR may be estimated as above. The easiest way therefore to handle multiple occurrences of the condition over a long study period is to shorten the time interval sufficient to make the constraints reasonable and give perhaps several rates e.g. one for each 30-day interval.

**Prevalence** is a static measure of disease frequency. It is the fraction of a population that is diseased at a point in time. It is a measure of existing cases based on one test or examination. For example a survey done, by examining once, a population of herds for the presence of TB results in a calculation of the prevalence of TB in the herd population under study at that time. The general formula for the calculation is:

\[
\frac{\text{Number of herds restricted (at a point in time)}}{\text{Number of herds at risk at that point in time}}
\]

Reference:
Paper 2.

Bovine Tuberculosis Eradication in Ireland

Margaret Good   Department of Agriculture & Food, Kildare St., Dublin 2

Abstract

In Ireland the bovine tuberculosis (BTB) eradication programme commenced in 1950 and became compulsory throughout Ireland by 1962. The initial driving forces for the programme were production losses in cattle, human health problems and a desire to trade in live bovine animals primarily store cattle to the U.K. While the operation of the programme ensures that production losses in cattle and human health concerns are no longer an active issue, the programme remains necessary to ensure that trading conditions may be met which possibilities expanded post 1965, as Ireland met European trading conditions for live animals. Despite strict adherence to testing and control measures exceeding those of countries that had eradicated BTB, the eradication programme in Ireland has not achieved the target of final eradication although the prevalence of BTB has been considerably reduced. Unlike in those countries, which have succeeded in eradicating BTB Ireland has a wildlife species (*Meles meles*) in which BTB is endemic sharing the same environment as bovine animals. Considerable research effort has been devoted to determining the contribution of wildlife to the BTB problem and in trying to develop a viable long-term solution to the wildlife issue. When the tools are finally developed to control the disease in wild animals, Ireland should at last achieve the target it set for itself in 1950.

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Paper 3


Good M, Duignan A

Department of Agriculture, Fisheries and Food, Kildare St., Dublin 2

Abstract

Under the Irish Bovine Tuberculosis (bTB) Eradication Programme all herds are subjected to at least one test per annum. The Single Intradermal Comparative Tuberculin Test (SICTT) is used in Ireland for the detection of cattle infected with *Mycobacterium bovis*. There have been concerns regarding the specificity of the SICTT, notably by farmers, and particularly in herds where the detection of a single positive animal in the absence of an obvious source of (bTB) infection could be perceived as a “false” positive. To address this issue the so-called ‘Singleton Protocol’ was established as part of the Irish bTB eradication programme. This protocol allows for the early restoration of free trading status to herds where a single positive animal was detected and where the herd was not confirmed as infected with *M. bovis* by epidemiological investigation, by *post mortem*, by laboratory examination, or by further test. This paper presents data from the 2005 to 2008 bTB programmes on the number of herds which were assessed and which qualified for inclusion under the ‘Singleton Protocol’ and the outcome for qualifying herds up to and including having status restored early as a consequence of inclusion in that programme. The outcome of this protocol reaffirms the reliability of the SICTT at current levels of infection. However as overall infection levels of bTB fall it is advocated that the ‘Singleton Protocol’ be continued as a monitor of herds in which a single positive animal is disclosed, to assess progress towards bTB eradication in Ireland.

Abstract

There has been a national bovine tuberculosis (bTB) eradication programme (BTBEP) in Ireland for many years. All cattle herds are tested at least annually using the Single Intradermal Comparative Tuberculin Test (SICTT). Further, abattoir surveillance is conducted on all animals at the time of slaughter. In the Irish BTBEP, a substantial number of confirmed bTB lesions are detected in non-reactor animals, to SICTT, from Officially Tuberculosis Free (OTF) herds at slaughter. In this study we investigate risk factors for non-reactor animals from OTF herds presenting with a confirmed bTB lesion at slaughter, but with no evidence of within-herd transmission.

A case-control study was conducted, with animal as the unit of interest. The case animals were all SICTT non-reactor animals slaughtered in 2012, with a confirmed bTB lesion identified during routine abattoir surveillance and with no evidence of within-herd transmission. Control animals were selected from all SICTT non-reactor animals slaughtered in 2012 from OTF herds where no bTB lesion was found. Four controls matched by age (+/- 1 year) and location (county) were randomly selected for each case. A conditional logistic regression model was developed for univariable and multivariable analysis.

The final multivariable model included: number of movements, herd type, herd-size, inconclusive reactor status at any previous test, abattoir and time spent in a herd restricted for bTB. The odds of being a case increased with the number of times an animal had moved herds. Animals from suckler herds were significantly more likely to be a case compared to those from beef herds. The odds of being a case decreased with herd-size and increased as the time spent in a restricted herd increased.

There were three key conclusions from this study. Firstly, the main risk factors for animals presenting with a confirmed bTB lesion at slaughter were: previous bTB exposure history, previous inconclusive reactor result at the SICTT, the number of herd movements and herd type/ size. Secondly, there was very limited evidence that these animals could have been detected any earlier. Finally, there is a need to reconsider the importance of abattoir surveillance during the latter stages of an eradication campaign. As herd prevalence declines, an increasing proportion of herd restrictions will be triggered by a single bTB-lesioned animal, with no evidence of within-herd transmission.

Keywords: Bovine tuberculosis; lesions; abattoir surveillance; latency; Ireland

Preventive Veterinary Medicine 126:111–120 doi:10.1016/j.prevetmed.2016.02.003
Depopulation

A study of Irish farmers, whose herds were depopulated as a result of bTB, 2008-2010.

James Casey - Department of Agriculture, Food and Marine, Kildare St., Dublin 2, Ireland

STUDY SIZE

This study documents Irish farmers' experiences of herd depopulation due to bovine tuberculosis (bTB). Depopulation is a control measure used when animal infection levels surpass 30%. Between 2008 & 2010, 9% of herds suffered a herd or partial herd depopulation. These herds accounted for 0.07% of all herds nationally restricted in this three-year period, and for 7% of all animals slaughtered as a result of bTB in the same period.

WHAT HAPPENED

- 90% had to be restocked with cattle.
- 91% full replacement
- 135 identified new herd health issues in new stock.

- The herd between 12,000 and 20,000 cattle for 10-11 years of hard improvements.
- With compensation to replace animals we went back to farming because we had a source of. We improved the plant to the best of our disposal ability, if we didn't move with the times, we would have gone to be unhired. It took 2-3 years to get back on cattle again.
- Purchased cattle turned out to be healthier than the depopulated herd.

SURVEY METHODS

Farmers were surveyed by postal questionnaire, telephone, and face to face interview. The rationale for the intervention of this group was that they were the farmers that have had the most running and greatest exposure to all aspects of the bTB eradication plan. These responses were used to test the postal questionnaire - was it useful? and telephone interviewing was far more effective in collecting information.

- 45% of all respondents, 28% (24% completo) 6% by telephone. No online replies were received.

CONTROL

"The most important things - a cow has 4 legs, with only one leg behind us. He never had a reactor."
"The TB test used is very expensive and a severely infected animal will not show any reaction to the test. So there are plenty of secrets escaping eradication.
"We would say, for welfare reasons if thought it was a good idea."

- 20% of respondents believed that the herd remained healthy since the occurrence.

HUMAN HEALTH

"My grandson was a driving force of this work. He was going to study veterinary medicine, but we wanted him to go work with me. I gave him a job. The farmer turned out to be successful. He had the confidence. He had no reason to wonder how positive the test is. Don't know whether we got one-and-only one sample that was a positive culture.
"One of our children developed TB as well."

MAIN EFFECT

"If I were a dairying milk farm. I'd be a super model.

- 20% of respondents believed that the herd remained healthy since the occurrence.

- If stress burned calories, I'd be a super model.

- The energy was a driving force of this work. We were going to be doing a lot of things. Let's stop now.

- The dairy cow went on the truck. In Ireland, every farmer has no stock. They sell them, he sells them, they sell them.

- This is part of our heritage. Our culture, we have a tradition. We know that they will be in a particular field.

- This is part of our heritage. Our culture, we have a tradition. We know that they will be in a particular field."
As Bovine Tuberculosis Eradication progresses post mortem detection becomes more critical.

Duignan, A., Kenny, K.

Department of Agriculture, Food and the Marine, Kilkare St, Dublin 2, Ireland

1 November 2016

What should you be looking for?
Lesions which could be tuberculous granulomas

What is a granuloma?
A granuloma is a lesion consisting of a fibrous outer layer around a cellular granular tissue which often has a caseous or purulent centre.

TB can affect almost any organ or lymph node in the body – most commonly the thoracic and head glands.

What is different about these lesions?
Are they all from cattle? Yes
Are they all from lymph nodes? Yes
Do they look similar? Yes/No
Are they all granulomas? Yes

What is your choice?
Which do you think are not TB? (Answers below)

Inspectors are the key to detection
Multiple incisions yield greater detection rates

Laboratory staff are the key to diagnosis
Only the laboratory can differentiate and confirm.

The more samples submitted, the greater confidence that TB is being monitored effectively.
Answers: (All TB except)
2. Actinobacillosis
6. Rhodococcus Equi
8. Actinobacillosis
11. Neoplasia
12. Parasitism
14. Actinobacillosis

References:
Paper 7

An outbreak of tuberculosis affecting cattle and people on an Irish dairy farm, following the consumption of raw milk from a cow with tuberculous mastitis
Paul Doran, John Carson, Eamon Costello, Simon J. More

Abstract

Bovine tuberculosis is an ongoing problem in Ireland, and herd incidence has remained at approximately 5% for some years. Spillover of infection from cattle to people remains an ever-present possibility, given the ongoing pool of infection in the Irish cattle population. This paper describes an outbreak of tuberculosis affecting cattle and people on a dairy farm, following the consumption of raw milk from a cow with tuberculous mastitis. During 2005, a substantial number of calves and people became infected on a farm in southeastern Ireland following the consumption of milk from a 7 year old cow with tuberculous mastitis. 25 of 28 calves born during autumn 2004 and spring 2005 were subsequently as TB reactors, and 5 of 6 family members were positive on the Mantoux test. During 2005, milk from this cow had mainly been used to feed calves, and was added only occasionally to the bulk tank. Therefore, the calves each received infected milk on an almost continuous basis between birth and weaning. The family collected milk from the bulk milk tank, and consumed it without pasteurization. This case highlights the risks associated with the consumption of raw milk. In this family, TB has had a very significant impact on the health of two young children. These risks are well recognised, and relevant information for farmers is available. It is of concern, therefore, that raw milk consumption remains prevalent on Irish farms. New strategies are needed, in partnership with industry, to address this important issue.


Paper 8

Progress in tuberculosis eradication in Ireland
Michael Sheridan

Abstract

Ireland ran a conventional test and slaughter Bovine Tuberculosis eradication programme from 1954 until 1988. This programme fulfilled our trading requirements but failed to eradicate TB. At this point a major initiative, ERAD, was launched targeted with reducing the disease levels by half within a four-year period and devising the strategy and supports necessary to achieve final eradication. The lessons learned at that time have informed Ireland's eradication programme ever since. Eradication was not possible without developing solutions to address the wildlife disease reservoir and other identified constraints. Since 1992 the programme objectives have been restated. It is now effectively an interim control programme where significant resources have been invested in research and development aimed at overcoming the identified constraints to eradication. Policy is informed by science and debate among stakeholders is generally knowledgeable and balanced. This paper outlines developments in recent years and sets out our expectations for progress in the period ahead.

Progress in tuberculosis eradication in Ireland Michael Sheridan Veterinary Microbiology, Volume 151, Issues 1–2, 5 July 2011, Pages 160-169
The impact of an integrated wildlife and bovine tuberculosis eradication program in Ireland

Michael Sheridan, 1 Margaret Good, 1 Simon J. More, 2 Eamonn Gormley 2

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Significant improvement in bovine tuberculosis (bTB) levels has been achieved in Ireland over the past ten years. This is attributed to a coordinated programme of control and eradication in both the cattle herd and also in the wildlife reservoir, the badger, underpinned by a comprehensive research and development programme. It is hoped that a new drive towards final eradication will commence in the next few years once the novel badger vaccination strategy has been proved and refined. At the end of 2011, 97.8% of cattle herds were officially bTB free. During 2011, 99.68% of animals were TB free.

The initial bovine tuberculosis eradication program in Ireland

While BTB was a major cause of production losses and indeed human illness in Ireland in the 1950s, it was primarily the prospect of a trade embargo with the United Kingdom that provided the impetus for Ireland to commence a national eradication programme. A BTB eradication programme had commenced in England in 1950 and rapid progress was being made. An initial voluntary pilot eradication programme commenced in Ireland in 1954. This was subsequently expanded and extended across the country, all herds were issued an individual herd number and an individual animal identification scheme was introduced. By 1962, the programme was both national in scope and compulsory in nature. Primary programme measures, included an annual single intradermal cervical comparative tuberculin test (SICTT) of all herds, follow up testing in diseased herds, compensation measures and a range of movement controls.

Substantial progress was made in the early years. Animal incidence rapidly fell from an initial 17% in cows to an average across all animal categories of just 0.44% by 1965. There was a parallel fall in total carcass condemnation rates for BTB, from 2.32% to 0.08% in cows. From that point forward, however, progress stalled and animal incidence remained stubbornly at approximately 0.5%. By 1968, the quality of testing by private veterinarians was being blamed for the lack of progress. Measures to improve test performance, including the employment of a dedicated testing task force, resulted in a further slight fall in disease levels but no substantive progress was made.

Tuberculosis (TB) in Irish badgers was first reported in 1974, but the significance of this finding was not appreciated at the time. Over the next 15 year. further epidemiological evidence gradually emerged to indicate that the disease was widespread in this species and to suggest that this could be a significant factor in constraining progress toward eradication of BTB. The national program had been formulated around the classical epidemiological model that assumed bovine-to-bovine transmission as the primary pathway, with much of this transmission occurring during the winter housing period when contact opportunities were greatest. In the mid-1980s, major stakeholder dissatisfaction gave rise to the creation, in 1988, of a new executive agency, Eradication of Animal Disease (ERAD), tasked with providing a more dynamic management of the program and reducing the disease levels by half within a four-year time frame. The ERAD board comprised all relevant stakeholder interests and its chief executive, Dr. Liam Downey, was given very considerable resources to achieve this objective. While history shows that ERAD inevitably failed in its primary disease reduction objective, the key legacy of the ERAD executive was a functional integrated management system and an insistence that national program policy be advised by good science. Thus, an effective platform was created for tuberculosis research in Ireland. Central to this was the creation of a dedicated BTB epidemiology unit known as the Tuberculosis Investigation Unit, since renamed the Centre for Veterinary Epidemiology and Risk Analysis; (CVERA). The remit of this unit was to investigate the factors; that militate against the eradication of tuberculosis in cattle at the national and regional level, and to identify means; of improving the rate of eradication. Thus commenced a program of research targeted with (a)
improving the diagnostic tools available for use in the program and (b) studying the role played by the badger in the maintenance of the disease in bovines. An important input to the future policy direction was provided in a confidential report prepared for ERAD in 1990 by Professor Roger Morris and Dirk Pfeiffer [1]. The broad conclusion of this report was that disease in wildlife posed significant constraints to the Irish program. They recommended a refocus toward “control at least cost” with the monies saved to be invested in R&D to overcome the identified constraints before subsequently relaunching the drive toward final eradication. This focus was restated in a subsequent economic analysis commissioned by ERAD the following year [2], with the authors recommending that Ireland “retain eradication as a long-term goal while taking the necessary steps to make that objective a reality. Only with new technology can eradication become possible.” In an intra-EU bovine trade context, the minimum control program that can be undertaken is set down in Council Directive 64/432/EEC. This mandates an annual test program and reactive measures where disease is revealed. Therefore, scope for significant savings was limited. Nevertheless, the formal restatement of objectives as set down by ERAD brought much-needed clarity to the program with consistent interim and long-term objectives to provide the strategic framework underpinning the management of the tuberculosis eradication program.

In 1991, responsibility for the BTB eradication program reverted back to the Department of Agriculture. Over the next 10 years, the program operated in compliance with Directive 64/432/EEC and an average of 30,000 reactor animals per annum (and in excess of 40,000 during the period 1998–2000) were culled from the national herd. In parallel, additional monies were allocated to provide the necessary scientific research to advise policy. The role of wildlife in the maintenance of BTB was investigated and technological advances were exploited to be better manage the program.

Wildlife

In the 1980s, numerous local studies were undertaken in counties Cork, Galway, Offaly, Longford and Kilkenny that showed an apparent improvement in BTB levels following the removal of the local badger population [3]. Tuberculosis in badgers was found to be widespread: a confidential consultancy report in 1990 postulated that the disease should be considered endemic in badgers, having crossed over from bovines at least 30 years previously, thus explaining the even geographic spread and stable prevalence within the species [1]. There was growing epidemiological evidence in support of ongoing transmission between badgers and cattle. Further evidence became available with the advent of strain typing from 1990 [4, 5]. Also during this period, Mycobacterium bovis infection was increasingly found in wild deer [6]. While this is postulated to have given rise to localized disease problems in cattle in some parts of the country, where infected deer are known to enter into cattle pasture, wild deer are generally considered a spill-over host for this disease [7].

The first major formal research project seeking to examine the contribution of badgers to the epidemiology of BTB in Ireland took place in east Offaly between 1989 and 1995. This was followed by the Four Area project, conducted in four different areas of Ireland from 1997 to 2002. These field trials were of major significance, with each comparing the incidence of disease in cattle in large areas of proactive badger removal and matched areas of minimal badger disturbance. In the East Offaly study, proactive badger removal was associated with a significantly reduced risk of confirmed TB breakdowns in associated cattle herds [8]. This effect was sustained: indeed, it continued to fall subsequent to the end of the trial in association with continued but less intensive badger removal. The results from the Four Area project were very similar, with proactive badger removal leading to a substantial and significant reduction in the incidence of BTB in the removal area compared to the reference area in every year of the study period in each of the four counties [9]. These studies provide compelling evidence of the central role played by badgers in the epidemiology of bovine tuberculosis in Ireland.

The epidemiology of M. bovis infection in badgers has been reviewed previously [7]. Badgers are considered to be highly susceptible to and an ideal host for M. bovis, tolerating the disease well [10]. TB kills relatively few badgers and does not significantly perturb population density or the size and structure of social groups. In a naturally infected population, infection is chronic and infected animals can present with latent subclinical infection (with no visible lesions or clinical signs of disease) to mild disease (with small pulmonary and extrapulmonary lesions) and to severe disease with generalized pathology. Within a badger population, infection with M. bovis is most frequently seen in its latent form [11]. The risk of transmission of infection is dependent on the stage of disease progression and the routes of exposure and excretion. While M. bovis infected badgers can excrete mycobacteria from the respiratory, digestive, and urinary tracts; as well as in exudates from skin lesions, transmission of M. bovis infection among badgers appears to occur mainly by the respiratory route. Although there is an overall trend for increased prevalence with age, the acquisition of infection may arise most frequently in young animals due to pseudovertical transmission from mother to cub and by aerosol and bite wounds in adults, particularly in the males. Because respiratory lesion are common whereas skin wounds are not, there is little doubt that aerosol is the main mechanism of
badger-to-badger transmission [11]. Although the mechanisms for transmission of infection among badgers are mostly understood, those between badgers and cattle remain to be characterized. Transmission between naturally infected badger and calves has been demonstrated in a housed situation after a lapse of six months. The transmission and maintenance of M. bovis in badger populations is a complex process in which many factors influence within-population prevalence and rates of transmission. The results of M. bovis strain typing studies provide evidence of extraterritorial movement of badgers. The discrimination of strains by spoligotyping and variable nucleotide tandem repeat (VNTR) analysis demonstrates that the interactions between badgers can result in coinfection of individual badgers with different strains [5]. The identification of these diverse VNTR profiles also suggests that different strains may be associated with the local prevalence of infection.

It has taken almost 20 years of research outlined above for the role of infected badgers to be clearly understood and acknowledged as the primary constraint to progress for the Irish BTB eradication program. A diagrammatic representation of the transmission model is provided in Figure 28.1.

![Figure 28.1 Transmission pathways for Mycobacterium bovis (Illustrations© Hannah More2013).](image)

**Current wildlife program**

Ireland is now implementing a comprehensive interim strategy to minimize transmission from wildlife while maintaining and enhancing the existing measures to control cattle-to-cattle transmission in parallel with a badger vaccine development program [12]. A new road map has been drawn with a dual program addressing both the disease in wildlife and the disease in bovines, with both programs fully supported and advised by scientific research.

By 2003, an agreement had been reached with the National Parks and Wildlife Service of the Department of the culling of badgers at the national level for disease control purposes. In 2002, the Department of Agriculture set up the Wildlife Unit, whose role is to deliver a targeted program that controls the densities of badgers in areas where cattle herds are identified with a concurrent, related TB problem [13]. Its activities are thus focused in areas of higher disease prevalence in cattle. These areas also have higher disease prevalence in badgers [11, 14]. In these high-prevalence areas, badger removal forms the basis of an interim disease control strategy where the goal is to reduce the badger population density in order to reduce the risk of transmission to cattle [15]. In addition work from Ireland has shown that proactive culling leads to a long-term decrease in TB prevalence in the re-emergent badger population [16]. Thus, the program aims to reduce the local population of badgers from the commonly encountered average starting density of 2-plus badgers per km to a level in the range of 0.2-0.5 badgers per km. An annual culling program is managed to ensure these lower density levels are maintained. Currently, badgers are culled on 28% of the national area of agricultural land—an upper limit of 30% applies, and between 5,000 and 6,000 badgers are removed per annum. The land area of Ireland is approximately 70,000km², including about 50,000km² used for farming. Badgers are captured on approximately 15,000km (28% of 50,000km²), on the basis of one capturing period per annum. The total badger population is estimated to be approximately 84,000 [17]. Data collection in association with current badger removal operations is playing a key role in identifying locations for further vaccination trials and ultimate vaccine deployment [13].

In contrast to reports from the United Kingdom [18], there is no evidence in Ireland linking badger removal with any increase in herd TB breakdowns in cattle, either during reactive removal [15] or on land surrounding areas of proactive removal [9]. Rather there is extensive field-based evidence in support of strategic badger removal as an effective method to minimize badger-to-cattle transmission. Targeted badger removal in County Laois between 1989 and 2005 showed a significant beneficial impact on the risk of future breakdowns [15].
By addressing this wildlife constraint, Ireland has succeeded in reducing BTB incidence and maintaining it at relatively low levels using a sustained cattle testing and strategic badger cull program. At the end of 2011, 97.8% of cattle herds were officially BTB free, and during 2011, 99.68% of animals were BTB free. BTB is no longer a threat to human health or to trade [12]. However, the ongoing costs of the disease control program remain a significant burden on the national Exchequer and the farming sector. M. bovis infection cannot be eradicated from Ireland without the reservoir of M. bovis in wildlife being adequately addressed [10]. Nonetheless, badgers arc afforded legal protection, and the options for dealing with the disease in this species must necessarily be constrained.

Wildlife vaccination studies

Once badger infection was identified as a possible constraint to eradication of BTB in bovines, in the early 1990s, the national BTB research program was refocused to address this new limitation. Culling of badgers could only be used in a very limited way because of their legal protected status. The feasibility of developing a vaccination program for badgers along the lines of the European fox rabies program was first considered in 1994, with input from scientists from Ireland and Northern Ireland [19]. Subsequently, a program for developing and proving such a vaccine was drafted [20]. Following a failed initiative, which sought to involve a number of European partner organizations under a framework-supported research program in 1996, Ireland commenced its own vaccine development program in 1998. The aim of vaccination is to reduce the prevalence of infection in the badger population or to change the expression of the disease and limit the rate of M. bovis excretion, thereby reducing the transmission of M. bovis between infected badgers and susceptible cattle.

In the early stages of the research program, very little was known about the pathogenesis of TB in the badger or about its immune system, or whether it could mount an effective immune response to infection. Detailed research has been conducted and is still currently underway jointly in both Ireland and the United Kingdom to address these deficits with a view to the development of an effective badger vaccine and the implementation of a strategic program of badger vaccination [10]. A range of in vivo diagnostic tests for badgers have been developed [7] and pen trials using M. bovis BCG have been conducted. Significant progress has been made in demonstrating that badgers can mount a protective immune response against TB and that BCG vaccine, when delivered by a variety of routes, including parenteral (subcutaneous and intramuscular) or mucosal (conjunctival and oral) routes, is effective in generating such a response in captive badgers [7].

An injectable BCG vaccine has been granted a license for use in the United Kingdom and a field trial of the vaccine has demonstrated that the vaccine reduced the number of bovis sero-positive badgers by up to 74%, compared with nonvaccinated badgers (Chambers, M. A., personal communication). A three-year oral vaccine field trial in badgers is currently nearing completion in Ireland with the aim of demonstrating that the protection observed in captive badger studies also occurs in wild badgers under conditions of natural M. bovis transmission, and to measure vaccine efficacy [21]. A badger vaccine deployment project is also being undertaken Defra in the United Kingdom using the injectable vaccine; the stated aim is to build confidence in the principle and practicalities of vaccination.

If eradication of infection in the targeted population is the objective of the program, uniform vaccination of the entire population, or a significant proportion of it, will need to continue until the last infected badger is removed from the population. However, some infected individuals will survive and live with TB for many years, and it is these animals that will determine the length of time that vaccination must continue. The optimal delivery system for vaccination of badgers at field level would be an oral bait system, and thus research into an oral delivery strategy is ongoing. In the interim, a further vaccination project has commenced in Ireland to vaccinate significant subpopulation s of badgers by means of a capture/vaccinate/release protocol using an intramuscular preparation in badgers caught in previously culled, low-density badger areas that had been burdened with high levels of TB in both cattle and badgers. This study will comprise a vaccinated area and a control area where culling will be maintained and wherein the levels of BTB will be monitored and compared.

Additional studies arc still required to address key components of the vaccine research program. The development of mathematical models will help to devise optimal vaccination strategies for reducing disease prevalence [21]. Additional captive badger studies to examine transmission between badgers (both vaccinated and nonvaccinated) and between badgers and cattle will help evaluate the level of vaccine coverage required to generate and maintain a threshold of herd immunity. Bait-uptake studies are currently being conducted, further to earlier work on badger diets in Ireland [22], providing information on the effects of season, population density, and diet on bait uptake. Studies in relation to the safety, efficiency, and product quality of the vaccine are now being carried out for registration of BCG for use in badgers.
**Cattle**

Since the early 1990s, a uniform comprehensive BTB testing and control program for cattle has been implemented in Ireland in conformity with the requirements of the EU trading ruling, Directive 64/432/EEC. All herds in the country receive an annual test using the SICTT with matched avian and bovine tuberculin. Additional testing is focused on infected and at-risk herds that emerge from the testing program, routine slaughter monitoring, and contact tracing of animals. Similar programs have been successful in eradicating BTB in other countries where wildlife hosts were not a constraining factor. Over the intervening 20 years, the Irish program has been progressively enhanced and refined through a series of operational controls and support measures that significantly exceed the baseline requirements of the EU legislation 112).

**Data handling systems**

The Irish BTB program benefits from excellent custom-designed data handling systems. These are fully integrated and provide accurate, real-time information allowing for in-depth analysis of performance and outcomes of various elements of the program. The Animal Identification and Movement System is a generic online animal identification and movement recording system that covers a number of animal species. It manages the herd numbers and other locations where animals are present, the issuing of identification tags and it record the births, movements and disposals of cattle.

The Animal Health Computer System is a modern fully networked, three-tier internet based Oracle database that records the full details generated by the 9 or 10 million animal tests carried out annually on the cattle population of over 6 and a half million animals originating from 117,000 herds. It facilitates traceability for disease control purposes, records epidemiological data for all TB outbreaks and investigations and operates various routine and risk-based testing programs.

Herdfinder is a multilayered GIS facility using ortho-photography and ordinance survey maps as a background on which to view the geographical relationship between an infected index herd, contiguous herds and topographical features. It also forms the basis for the wildlife unit software, which maps badger sells (burrows) throughout the country and facilitates the management of the wildlife program.

**Measuring performance in the context of the bovine TB eradication program's statement of objective**

Data systems such as those described here, in addition to facilitating routine operations management, provide for the use of any number of indices for measuring the overall performance and outcomes of the BTB program. The measures used routinely include the following:

- Percentage of herd tests completed within the year
- Number of reactors
- Number of visible lesion reactors at routine postmortem
- Reactor animals per thousand animal tests
- Herd disease incidence
- Disease-free herds as a percentage of all herds
- Animal disease incidence
- Reactor animals per thousand population
- Duration of restriction
- Average number of reactors per restriction
- Singleton breakdowns as a percentage of all breakdowns

Some measures are best suited to assess the effectiveness of surveillance (e.g., herd incidence, percentage of herds remaining disease free), while others give a perspective of the effectiveness of the controls used once the infection is detected (restriction duration. number of reactors per restriction, percentage singleton breakdowns, numbers of reactor retests, inter-episode interval. repeat restrictions). The Irish eradication program applies different measures as appropriate for assessing both surveillance and control using the online data sources.

Ultimately, reactor numbers and the number of herds restricted per annum are seen as the primary indices of disease. These measures in turn are directly related to the volume/frequency of testing and the specific performance of the test. Ireland has used a uniform uninterrupted standard EU-mandated annual screening program since 1992. Variation in total testing volumes arises solely as a consequence of disease detection in the primary screening program. In addition, Ireland has standardized the tuberculin test and its implementation. The primary index of disease at animal level continues to be the number of reactor animals per thousand tests carried out, as this takes into account testing volumes.

A Value for Money and Policy Review was carried out on the Irish program in 2008 in the context of assessing program performance against the stated interim objective [12]. The author proposed that the stated
objective of the program, “to control bovine tuberculosis at levels consistent with maintaining trade in bovine animals and their products, at minimum cost to the Exchequer, while overcoming the constraints to eventual eradication through investment in research and technology” should be clarified with the following statement:

As long as the constraint imposed by the existence of an infected wildlife reservoir continues to exist, progress toward the interim objective will be considered adequate if the herd incidence, the absolute number of reactor animals and the number of reactor animals per thousand animal tests (APT) continue to follow a declining trend as represented by the respective five-year exponential moving averages. The interim objective will be formally reassessed in 2013, at which time it is expected that research into badger vaccination will have reached a point that will enable projections to be made as to its likely long-term impact on bovine tuberculosis.

The use of five-year moving averages applied to three standard indices of disease provides a useful yardstick for communicating future progress for program managers.

**Measuring outcomes in the context of other national programs**
Within a European perspective, international comparison of performance is inevitable but often contentious. Even within neighboring jurisdictions, there are significant differences in recording, processing and interpreting data which, in association with differing outcome definitions, make comparisons difficult. An initial study to address this problem has found that the TB eradication program in Ireland has made significant progress in recent years compared to the programs in England, Wales, and Northern Ireland [23].

**Program quality assurance**
The standard operating procedure for the performance of the single intradermal cervical comparative tuberculin test (SICTT) and the standards expected are set out in the annual contract document signed by the participating veterinary practitioners [12]. Procedures are also set down for response to less than satisfactory standards of testing by contracted veterinary practitioners [12]. Compulsory training courses are provided for all new recruits to the program, and retraining is provided for those whose performance is deemed unsatisfactory. Standard operating procedures for other program elements, such as risk assessment, risk categorization of herds, test prioritization, management of diseased herds, epidemiological investigations, use of supplementary tests and so on, are set out in the “Handbook for the Veterinary Management of Herds under Restriction due to Tuberculosis” [12]. Over the years quality control elements have been enhanced and incorporated into the Irish BTB eradication program. As well as the items above, these relate to the quality of the tuberculins used, testing supervision, equipment (e.g. McIntosh multidose syringes used in the program are subject to a formal service and certification process on an annual basis), laboratory supports, the uniformity of postmortem procedures, and the validation of reactor status [24].

In 2011, some 95% of a total of 8.33 million animal tests were carried out by 1,100 private veterinary practitioners, and 18,531 reactor animals were removed [12]. The tuberculin used in the Irish program is supplied by Prionics Lelystad BV. The contract specifications are for a protein-purified derivative (PPD) potency of 3,000 IU/dose for a 0.1 ml dose (Bovine) (66%-150%; i.e. between 1,980 and 4,500IU) when tested in guinea pigs sensitized by living M. bovis strain AN5. The avian tuberculin PPD should have a potency of 2,500IU/dose for a 0.1 ml dose (avian) (75%-133%; i.e. between 1,875 and 3,325IU) per dose when assayed in guinea pigs sensitized with heat inactivated M. avium. The pairs of tuberculin PPDs, for the SICTT, must not exceed a maximum potency difference of 500 IU per dose between both (avian and bovine tuberculin) in the tuberculin PPD kit. Packaging is designed to minimize waste and facilitate specific matching of avian and bovine batches. Ireland undertakes potency testing of its tuberculin on naturally sensitized reactor cattle two or three times each year to ensure quality and uniformity of product.

Because the program is now so computerized with all relevant information captured directly, data analysis, for the purpose of quality control, is greatly facilitated. In particular, the testing performance of private veterinary practitioners and the quality of abattoir postmortem performance are subjected to routine QC analysis. Abattoir postmortem outcomes are used both in relation to rates of lesion detection in reactor animals and, equally important, in relation to submission and confirmation rates from animals that have passed their annual test but subsequently are found to have suspect BTB lesions on routine slaughter.

**Improvements in diagnostics**
Apart from the quality control aspects of testing and tuberculin, Ireland has embraced most international improvements in diagnostics within the European Union, of many of these. The Bovigam Interferon-γ (IFN-γ) assay is used as a supplementary test in conjunction with the SICTT in severely infected herds or groups of animals where the reduced specificity is considered acceptable. The INF-γ assay is targeted at herd with a high probability of containing infected animals or at those herds chronically infected over a number of
Anamnestic ELISA testing is used in circumstances where detection patterns indicate that an animal anergic to the SICTT is present in the herd and causing problems [12].

Work continues toward the development of a blood test for BTB with sensitivity and specificity comparable to that of the SICTT. In Ireland, this would address the logistical difficulties with the SICTT which necessitate the collection and presentation of all animals twice within a 72 (+/-4)-hour interval. A blood test, particularly a serum-based assay, would remove individual subjectivity and variation in test performance and require only one collection and presentation of each animal. In addition, a blood sample would open the possibility to conduct a laboratory screen for multiple diseases simultaneously. Most recently DAFM collaborated with Enfer Scientific in their endeavors to develop a multiplex ELISA assay utilizing various individual BTB antigens. This assay looked very promising initially [125] but less so when trialed over a large natural population. Nonetheless, work is ongoing, seeking to improve test sensitivity and specificity.

DNA fingerprinting of strains has been used to study the dynamics of TB in animals and to investigate links between infections in farmed and wild species. Most prevalent RFLP types are widely distributed and present in both cattle and badgers, providing evidence of cross-species transmission [5]. In Ireland, the combination of spoligotyping and MIRU-VNTR typing has proven to be superior to either test alone in revealing the diversity of M. bovis strains circulating in cattle and badgers [26] and assisted in the development and acceptance.

**Ongoing research on immunodiagnostics**

The advent of DNA-based tests in the form of the polymerase chain reaction (PCR) promised to herald a new era in diagnostic technology. The application of PCR requires a DNA target sequence to be present at minute or higher concentrations. Such a target might be found in sputum or feces of heavily infected animals. However, nowadays with sophisticated surveillance systems in place that facilitate the identification of infected cattle at an early stage of the disease cattle arc rarely clinically diseased to the extent that they persistently shed M. bovis. The majority of these animals are readily identified by using the tuberculin test and/or the IFN-γ assay. As more animals are tested at relatively short intervals, diagnosis is focused on the early postinfection stage, before the animal is likely to be highly infectious and excreting the tubercle bacillus in numbers that favor detection that is, once lesions are generated. Thus, as shedding of M. bovis is sporadic, this restricts the reliability of any diagnostic test that directly targets the M. bovis bacillus.

With the completion of the bovine genome sequencing project, it is probable that many new host response markers of infection will be identified that may serve as targets for novel diagnostics. Technologies are improving rapidly that will help increase our understanding of the host/pathogen interactions. It is likely that following infection, the host responds with a cascade of co-coordinated immunological events that ultimately dictate the outcome of the infection. Studies conducted at University College Dublin have shown that antigenic stimulation of peripheral white blood cells from M. bovis infected cattle induced measurable changes in gene activity that could be differentiated from nonstimulated cells [27]. The results of these studies suggest that there is a multitude of target genes that remain to be exploited for the development of novel diagnostics in this field alone.

The options for diagnosing TB in badgers include clinical examination, Pathology, or immunological assays, with each of these methods exhibiting different degrees of sensitivity and specificity. Clinical diagnosis lacks both sensitivity and specificity, as only those animals with advanced disease or with suppurating skin wounds exhibit clinical signs. Clinical samples –fecal, urine, wound exudates and tracheal aspirates- for culture for M. bovis have also proven to be a poor indicator of disease [11]. Therefore, reliable diagnosis of TB in badgers is dependent on detailed laboratory testing. The most sensitive and specific diagnosis of TB in badgers is achieved by postmortem examination with bacteriological confirmation of gross lesions or bacteriological examination of NVL tissues [11]. However, it has been established that increasing the resources used in the examination-for example, the inclusion of bacteriology-and increasing the number of tissues examined improve the detection rate of infected animals [7]. The results of these studies have shown that the actual infection prevalence may have been at least three times higher than the lesion prevalence previously reported.
The first immunological assay developed (in the Veterinary Laboratories Agency in the UK) for TB in live badgers was the Brock test, an indirect ELISA detection of antibodies against the M. bovis-specific antigen, MPB83, whose expression is high in wild type M. bovis. The overall sensitivity of this test is relatively low: about 40% of badgers with postmortem and culture evidence of infection test positive with this assay. Since then, a variety of assays have been developed based on the cell-mediated immune response, including lymphocyte transformation assay and badger IFN-γ assay and the humoral response. Stat-Pak rapid test and multiantigen print immuno assay (MAPIA) [7]. These tests offer improved sensitivity and specificity over the Brock test and are currently being used in captive animal studies and field trials.

Centre for Veterinary Epidemiology and Risk Analysis
In 1989, the Tuberculosis Investigation Unit was established in the Veterinary College in University College Dublin under the Directorship of Professor Dan Collins to provide epidemiological support and analysis to the national BTB eradication program. In 2004, the unit was renamed the Centre for Veterinary Epidemiology and Risk Analysis (CVERA: www.ucd.ie/cvera), and its brief was expanded to cover a wider range of international, national and local animal health matters. CVERA provides core support to the BTB program through two broad mechanisms: scientific support and scientific research. The former draws on in-house expertise in veterinary epidemiology, database management, geographic information systems and statistics. The latter includes a broad portfolio of research projects, which at their basis are seeking to address those key questions that, if answered will make the greatest difference toward control and eradication of BTB in Ireland. The research work relates to BTB (improving surveillance, improving management of high-risk herds, supporting studies), the role of wildlife in BTB (improving understanding of ecology and BTB epidemiology) and contributing to national BTB eradication policy (the national program, quality control). CVERA staff work closely with both national and international collaborators, the latter from a range of countries including Canada, France, the Netherlands, New Zealand, the United Kingdom, and the United States. Further detail is available in the biennial report [28]. Some key perspectives provided by the work of the Tuberculosis Investigation Unit/CVERA include many publications covering the following subject matter:

* Clarification of the relative importance of cattle-to-cattle transmission in the epidemiology of BTB particularly once annual testing of cattle had become well established. Studies showed that cattle-to-cattle transmission is relatively uncommon under Irish conditions and although brought-in animals have been identified as an important cause of herd break-downs in Ireland, there is generally little evidence of transmission from each primary case.
* Clarification of key risk factors for BTB breakdowns in Irish cattle herds including location, past BTB history and herd size.
* Evidence of residual infection in cattle emerging as a significant cause of breakdowns in recent years including the increased future disease risk associated with inconclusive reactor animals.
* Estimation of the test characteristics of current and potential TB tests in cattle under Irish conditions including the INF-γ assay, the SICTT and a multiplex immunoassay, and clarity concerning the performance of the SICTT using PPDs of different potencies and from different manufacturers.
* Evaluation of the relative effectiveness of abattoir surveillance.
* Conclusive evidence of the role of badgers in the epidemiology of BTB, based on results from both the East Offaly Project and the Four Area Project
* Work in support of the Kilkenny badger vaccine trial to enable quantification of vaccine effects under field conditions, including separate estimations of vaccine efficacy for susceptibility and for infectiousness.
* Support toward the development of robust systems of Quality control within the national program.
* Contribution to international work seeking to clarify the role of genetics in animal disease.

In many BTB eradication programs premovement testing plays an increasingly important role in protecting clear herds from reintroduction of disease. The benefits of this control measure are less clear in Ireland where full annual testing program are operating and where the main driver of the disease is external to the testing program that is wildlife. An assessment of the benefits and costs associated with premovement testing within Ireland [29] found that although there is much between-herd movement of cattle only 0.7% of destination herds became restricted as a consequence of these movements. Further the presence of recently introduced animals among the “reactor pool” is not conclusive evidence that introduced animals were the source of infection. The result of the study again highlighted the association between infection risk and previous herd history. The study concluded that cattle movement plays only a limited role in BTB spread in Ireland (explaining only 6%-7% of new herd restrictions). Consistent with these study results, individual animal premovement testing is not a requirement under the Irish BTB eradication program for internal animal movements but remains advisable for animals entering breeding establishments and compulsory for
international movement. The study did find that infection risk is greater in the herds that had previous breakdowns either as a result of cattle-to-cattle transmission (from residually infected cattle on the source or neighboring farms) or transmission from the environment, wildlife or human consistent with earlier work [9]. In the Irish BTB eradication program herds with a history of TB infection and those in areas contiguous to active infection are targeted for more frequent testing than the minimum annual herd test thereby curtail the opportunity for movement of potentially infected animals from such herds [12].

**Progress to date**

**Cattle**

The current BTB eradication strategy is leading to ongoing improvement in the national BTB situation. The herd incidence of disease in cattle has fallen from 7.5% in 2000 to 4.2% in 2011 and the number of serious breakdowns has reduced significantly. Further, the number of reactors has declined from an average of 33,000 in the 1990s to 18,531 in 2011 (Figure 28.2). This is the first time reactor numbers have fallen below 20,000 since the nationwide compulsory test and cull program for bovines began 60 years ago.

A degree of temporal and spatial variability in the various outcome results is apparent from year to year. Arising from this, five-point exponential moving averages of parameters such as herd incidence and reactors per thousand tests are used in assessing the performance of the program. These outcome variables are shown for the period 2002 to 2011 to reflect the period of operation of the wildlife unit (Figure 28.3). Both parameters have shown substantial improvement over this period.

The spatial distribution has changed somewhat, leading to a reduction in the size and intensity of BTB problem areas. Progress has been more marked in some areas, especially in the southwest and northeast (Figure 28.4).

![Figure 28.2 Reactor animals identified per annum, 1959-2011.](image1)

![Figure 28.3 Five-year exponential moving averages for reactor animals per thousand tests (APT) and for herd incidence, 2002-2011.](image2)
Figure 28.4 Density of TB incidence per square kilometer for 1999 and 2011 (kernel density with a search radius of 10km).

**Badgers**

The outcome of the interim population control program is a significant reduction in the risk of badger-bovine transmission through both the reduced badger numbers and the reduced burden of infection in the residual badger population. Badger vaccination against M. bovis infection has been shown to be effective experimentally and trials to assess its effectiveness in field conditions are nearing completion.

**Future progress**

The current BTB eradication program has been shown to be fully capable of reducing and ultimately eradicating TB from cattle herds. In Ireland, however, the ability to eradicate tuberculosis from cattle at the national level is constrained while infection continues to spread from badgers. The interim badger control program coupled with a comprehensive BTB eradication program has made significant progress in reducing infection levels in both species. However, this is limited by the numbers of badgers that can be removed and the percentage of the agricultural land that can be subject to badger population controls. Ultimate success is dependent on further reducing the level of infection in the badger population; to achieve this vaccination is the only strategic option available. Providing scientific support for the incorporation of BCG vaccination of badgers into the national BTB eradication program is the ultimate goal of the badger research studies. Although research has yet to be completed particularly with respect to vaccine efficacy and cost-effective vaccine delivery each in field situations there is good reason to be optimistic that effective badger vaccination can be implemented nationally within a three-to five-year time frame and that it will contribute to the enhanced control and ultimately the eradication of tuberculosis from the national cattle herd. In these circumstances, the time frame for eradication, for the first time in the history of the program becomes short to midterm perhaps as short as 15 years after a vaccine roll-out. What is certain is that significant progress is now possible.

Supplementary information, including a full bibliography, is available at http://www.agriculture.gov.ie/animalhealthwelfare/diseasecontrol/bovinetbbrucellosiseradicationschemes/diseaseeradicationtbbrucellosis/.

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Paper 10

Understanding and managing bTB risk: perspectives from Ireland

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Abstract

There is substantial variation in herd risk for bovine tuberculosis (bTB) in Ireland, with most herds playing little to no role in the ongoing endemic. In infected areas, bTB persistence (affecting one or a group of herds) is a key feature of the infection. In this paper, we present our current understanding and management of bTB risk in Ireland, based on a detailed review of research and policy. There is close interaction between science and policy in Ireland, seeking both to understand and effectively manage bTB risk. Detailed research on bTB persistence is presented, including current understanding of the relative importance of different infection sources, which can include residual infection in cattle and/or re-infection, either from local sources or following cattle introduction. In recent years, there have been three primary drivers for policy change, including scientific advances, ongoing improvements to programme supports, and ongoing programme review. In this review, three key future programme challenges are identified. Although good progress is being made, eradication has not yet been achieved. A key question concerns the additional effort that will be required, to move towards final eradication. Secondly, a percentage of non-infected animals are falsely positive to current testing methods. This is an ongoing challenge, given the imperfect specificity of test methods but will become more so, as the positive predictive value falls with reducing bTB prevalence. Finally, there is a need to re-engage with the farming community, so that they play a much greater role in programme ownership.

Key words

Bovine tuberculosis, Ireland, science, policy, risk, persistence

Highlights

- This paper reviews current understanding and management of bTB risk in Ireland
- Science is an important driver of bTB policy in Ireland
- There is substantial variation in herd bTB risk
- bTB persistence (affecting one or a group of herds) is a key feature of infection
- The relative importance of different infection sources is increasingly understood

1. Introduction

There is substantial variation in herd risk for bovine tuberculosis (bTB) in Ireland, with most herds playing little to no role in the ongoing endemic. During 2003-12, there were 4,391 herds (3.7% of circa 120,000 extant herds) that had experienced \geq 2 high risk breakdowns (1,064 (0.9%) \geq 3, 263 (0.2%) \geq 4 and 52 (0.04%) \geq 5), with a high risk breakdown defined as a period of herd restriction during which \geq 2 infected animals were identified, either by field or abattoir surveillance. In general, outbreaks present as spatio-temporal clusters in defined localities. Local ‘hot spots’, where long-lasting clearance has proved difficult, have been a key feature of bTB in Ireland.

In this paper, we present our current understanding and management of bTB risk in Ireland, based on a detailed review of research and policy. We also consider reasons for bTB persistence, relevant policy responses, a critical review of national progress towards eradication, future challenges and additional thoughts.

2. Linking science and policy

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In Ireland, science and policy are closely linked (More and Good, 2006), with scientists addressing the what (what are the key factors that influence bTB risk, locally, in herds, among animals?) and the why (what is the biological basis behind the observations?) and policy-makers considering the how (how are observed risks best managed?). Three research groups (the Centre for Veterinary Epidemiology and Risk Analysis, the TB Diagnostics and Immunology Research Centre, and the Badger Vaccine Project), have made substantial contributions to policy development since the late 1980s (Sheridan, 2011). There are regular meetings, both formal and informal, between scientists and policy-makers, focusing on both the broader picture (strategic research direction, project and personnel management, research output, external linkages) and on details relevant to specific projects. In Ireland, there has generally been little input from industry and other stakeholders on issues relating to strategic research direction other than expressing a desire that any programme modifications would be supported by research evidence.

3. Understanding bTB risk

In this section, we focus on two related, but distinct, issues:

- Section 3.1 considers herd-level risk factors for bTB presence (whether a herd is test positive or not at a point in time, alternatively), and
- Section 3.2 on reasons for bTB persistence (the ongoing or repeated presence of bTB in a herd or locality despite control efforts).

3.1 Herd-level risk factors for bTB presence

Extensive research has been conducted on herd-level risk factors for bTB in Ireland. Over a broad range of studies, three factors have consistently placed herds at greatest risk of being diagnosed with bTB, namely herd size, location (including bTB prevalence in the area) and bTB history.

3.1.1 Herd size

bTB risk increases with herd size, for reasons that are not entirely understood. Increasing herd size may increase opportunity for exposure, both within the herd and from neighbouring herds (Griffin et al. 1996; White et al. 2013). In addition, herd-level specificity will decrease as the number of individuals being tested within each herd increases (Martin et al., 1992).

3.1.2 Herd location

bTB risk is also associated with herd location, with area-level prevalence and with infection in contiguous herds, leading to the spatial clustering observed. bTB is more likely to occur in groups of herds, rather than in isolation, leading to local persistence of infection. This is discussed in detail later.

3.1.3 Herd bTB history

Finally, many studies have highlighted the impact of bTB history on future risk (Olea-Popelka et al., 2004; Wolfe et al., 2009; Clegg et al., 2011b, 2013; Good et al., 2011; Gallagher et al., 2013). Olea-Popelka et al. (2004) first investigated this issue in detail, using a retrospective cohort study of Irish herds with (‘exposed’) and without (‘non-exposed’) bTB in 1995. Exposed herds were categorized into five increasing exposure-severity classes, based on the total number of standard SICTT (single intradermal comparative tuberculin test) reactors detected during the breakdown. Focusing on the hazard of a future multiple standard reactor breakdown, and compared to non-exposed herds, the hazard ratios ranged from 1.6 for exposed herds with only 1 standard reactor up to 2.9 in exposed herds with 8 or more standard reactors during the 1995 restriction. Thus, the hazard of a future breakdown was clearly linked to exposure-severity class. Presumptive bTB lesions in reactor cattle were not predictive of future breakdown hazard having controlled for other factors.

Several recent studies have taken this issue one step further, seeking to understand the longer term significance of past bTB history. In other words, will future bTB risk be influenced by bTB history going back 1, 2, 5 or more years? Each highlight the importance of bTB history on future risk. Each also suggests that the longevity of this risk is substantially longer than previously thought.

White et al. (2013) conducted a case–control study on the association between bTB restrictions in index herds in 2006 and in neighbouring herd(s) (within 1 km) in previous years, while controlling for each herd’s bTB history and other risk factors. Past bTB history was found to be a significant risk factor for bTB recurrence, both of the neighbouring herds up to 2 years previously, and in the index herd up to 5 years previously. Indeed, after controlling for all other variables in the model, herds with an bTB restriction 5
years previously were 1.39 times more likely to suffer a bTB recurrence than herds without a bTB restriction during the last 5 years. In other words, bTB history was important, both in the index and neighbouring herds, with the effect persisting longer in the former.

Clegg et al. (2015) considered the longevity of herd bTB risk in greater detail, to help refine existing policy and to support decision-making with respect to the enhancement of risk-based controls on herds following a restriction. Of the 111,214 ‘clear’ herds with ≥1 full herd test during 2012, the study compared those that were (4,479, 4.0%) and were not (106,735, 96.0%) restricted (with ≥1 standard reactor or visible lesion at slaughter). Consistent with previous studies, risk factors influencing the probability of a herd being restricted in 2012 included bTB history (both the severity of and time since the last breakdown), herd size, number of adult animals purchased in the previous year, county incidence rate and the proportion of cows. Consistent with earlier studies, future risk increases with both increasing severity of, and decreasing time since, the previous restriction. Of particular importance, the study also suggests a future risk greater than baseline in those situations where the previous bTB restriction was both minor (a single standard reactor or lesion at slaughter) and many years previous. This suggests local persistence of infection (more likely in the locality rather than the herd) over relatively long time periods.

The introduction of cattle contributes to the establishment of bTB in Irish cattle herds. Herd bTB risk increases in association with an increase in the numbers of animals introduced (White et al., 2013). Further, the movement of animals in Ireland is substantial (Ashe et al., 2009), with animal-level bTB risk increasing with prior bTB exposure (Olea-Popelka et al., 2008; Wolfe et al., 2009). Nonetheless, the proportion of herd bTB restrictions attributable to introduction is relatively low, approximately 7%, based on analyses conducted on national data from 2003-04 (Clegg et al., 2008) and 2012 (Clegg et al., 2015). These estimates were determined after evaluating the movement and related herd bTB history of all herds restricted in Ireland during these two 12-month periods. The estimates were underpinned by several assumptions. Firstly, exposure was used as a proxy for infection. Secondly, the studies focused solely on recently introduced animals, ignoring the potential for latency (animals becoming infected following exposure but passing at least one test following introduction). Departure from these two assumptions will result in opposing effects on the estimate (departure from the former will over-estimate risk, and from the latter, the converse) (Clegg et al., 2008). Lane et al., in preparation, have assessed data on animal movements over a 3-year period focusing on the 402,365 animals that moved into herds that subsequently had a bTB breakdown. Only 0.44% of the animals that were tested within two months of moving into such herds were skin test positive at that test. The odds ratio for bTB positive skin test increased (P > 0.01) with increasing length of time in the herd of destination and with the higher risk category for the next test type scheduled for that herd. As for the Clegg et al. (2008) study this indicates that the risk was dominantly associated with the herd rather than with the animal that moved and the risk type of the test in the destination herd indicates these to be herds or herds located in areas where infection prevalence had been high. Further analysis is ongoing into the herds from which the test positive animals originated to evaluate their predictive risk prior to their outward movement.

3.2. Reasons for bTB persistence

3.2.1 General comments

In general terms, the problem of bTB persistence, either in a herd (herd recurrence) or a locality (local persistence), can be attributed to residual infection in cattle and/or re-infection, either from local sources (such as spread from environment, wildlife or farm-to-farm) or following cattle introduction. In recent years, there has been considerable research in Ireland on this issue, and substantial gains in understanding have been made. However, it has not generally been possible to be conclusive about either the role or relative importance of each of these different infection sources due, in part, to the broad-ranging control measures employed following high-risk breakdowns, which focus on both the herd and the locality. In such situations, it is often difficult to disentangle the relative importance of each infection source.

In Ireland, bTB-infected herds cluster in space, as outlined previously. Kelly and More (2011) found that spatial clustering persisted throughout a 5-year period of proactive badger removal (in the removal areas of the four area project). Badger numbers were substantially reduced, and this effect can be attributed to environmental contamination, residual (persistent but undetected) infection in cattle, and ongoing herd-to-herd transmission.
Good et al. (2011) evaluated the impact of full herd depopulation during 2003-05 on bTB recurrence, by comparing the future history of herds depopulated as a result of either bTB or BSE. In Ireland, the bTB depopulation policy is broad-ranging, focusing on all known drivers for bTB recurrence, including infected cattle, environmental contamination and, since 2000, a wildlife reservoir. Therefore, additional measures were employed during bTB (but not BSE) depopulation. Contrary to earlier depopulation studies in Ireland (Hahesy et al., 1992, 1996), the study found no significant difference in future bTB history, when comparing herds depopulated for bTB (by definition, those of high bTB risk) and BSE (those with no or a low previous bTB risk). Therefore, bTB depopulation during this period was effective in significantly reducing bTB risk, both in the herd (as a result of depopulation of infected cattle) and the locality (as a result of disinfection, delayed restocking to limit environmental contamination, contiguous testing and local badger removal).

Clegg et al. (2008) investigated the future bTB risk of 390,365 animals following derestriction of all Irish herds (n=3,947) during the 12 months from 1 October 2001. These herds had all previously been restricted following the detection of ≥2 standard reactors or bTB-lesioned animals. In total, 55,410 (14.2%) animals subsequently moved to new herds during the period between derestriction and the next full herd test, whereas 334,955 (85.8%) did not. The source herds were more likely than the destination herds to be located in areas where infection prevalence had been high for some years. Further, individual animal risk increases with increasing residence time in a herd following derestriction. Infection risk was significantly greater among non-movers (0.47%, 95% CI = 0.45-0.49%) compared to movers (0.22%, 0.18-0.26%). Further, among non-movers, infection risk increased with increasing time since de-restriction. Infection risk is greater in the source (compared to the destination) herds, either as a result of cattle-to-cattle transmission (in this case, from residually infected cattle in the source herd or on neighbouring farms) or transmission from the environment, wildlife or humans. Again, the relative importance of each cannot be determined from this study.

3.2.2 The importance of residual infection in bTB persistence

i. General

A number of studies are providing insights into the importance of residual infection (that is infected, but undetected, cattle) in the epidemiology of bTB in Ireland. Berrian et al. (2012) conducted a retrospective cohort study to determine the bTB risk among animals moved from unrestricted herds during 2005. Comparison was made between animals moved from herds that had been restricted at some stage during 2005 (‘exposed’) compared with those that had not (‘non-exposed’). The overall risk of a bTB diagnosis during the two-year period after the animals were moved was 0.69%, with animals from ‘exposed’ herds being 1.91 (1.76-2.07) times more likely to test positive compared with animals from ‘non-exposed’ herds. The impact of control measures during a bTB restriction was substantial, with animals moved before the herd restriction date having a significantly higher risk of being classified as bTB positive compared with animals moved subsequently.

Similar results were obtained by Wolfe et al. (2009), who investigated the future bTB risk in cattle sold from dairy herds with a recent bTB history. In this study, comparison was made between animals from exposed herds (those experiencing a recent bTB restriction) and unexposed herds (those that did not). A number of risk factors were identified, including cow-herd size, and an interaction between age and sex. In addition, there was a trend of increasing risk with increasing exposure, for cattle moved within 7 months of herd derestriction following a bTB episode. In comparison with unexposed herds, animals from herds with 1-7 reactors were 1.23 (0.87-1.74) times more likely to test positive, and animals with 8 or more reactors were 1.77 (1.06-2.96) times more likely to test positive. This study provides evidence in support of persistent infection following large breakdowns of 8 or more total reactors. It was postulated that large breakdowns are associated with active within-herd transmission, both preceding and during herd restriction (Wolfe et al., 2009).

In Ireland, as elsewhere, bTB breakdowns are first detected through either field or abattoir surveillance. The latter is particularly important in Ireland: up to 36% of bTB breakdowns between 1995 and 2010 were first detected using this method (Abernethy et al., 2013). In approximately 80% of these breakdowns, no further reactors are detected at a full herd retest (the factory lesion test, FLT) (Olea-Popelka et al., 2008). In a detailed study comparing breakdowns where further reactors were and were not identified at the FLT, risk factors for additional reactors were each broadly linked with past bTB exposure. The risk factors varied depending on whether the index animal (the animal with gross lesions during abattoir surveillance) was
introduced or homebred. If the index animal had been introduced, increased risk was associated with both
the index herd (the number of months that the index animal had been present in the herd, the herd size, the
number of contiguous herds) and the index animal (whether the animal had been present in a bTB episode
in a previous herd). If the index animal was homebred, risk increased with a range of herd-level factors
(time since last test, herd size, number of contiguous herds) and decreased with animal age. If the animal
had been in a previous bTB restriction, risk increased with increasing time since this restriction. These
results highlight the risk associated with a previous bTB episode, with this risk increasing with time and,
reasonably, the opportunity for transmission of infection to cohort animals. If the animal had not been in a
previous bTB episode, risk decreased with time that the index herd was clear of bTB.

ii. Inconclusive reactors

In recent years, a detailed study focused on the short- and long-term bTB risks of standard inconclusive
reactors (SIRs, animals with a bovine response >2mm and between 1 and 4mm greater than the avian
response) to the SICTT (Clegg et al., 2011b,c). The study was conducted on SIRs in otherwise bTB-free
herds, thereby avoiding potential confounding factors caused by variations in test interpretation (as would
occur if reactor animals were detected concurrently). SIRs (and TIRs; ‘transient SIRs’ these being SIR
animals with a negative SICTT result at the subsequent inconclusive reactor retest) had a higher risk of
being declared bTB positive, compared to SICTT –ve cohort animals from the same herd, at each of four
different periods of interest, as follows:

At slaughter, following an inconclusive response: SIR animals were more likely to be slaughtered
(reflecting an increased perception of risk among farmers) and positive at post-mortem (Clegg et al.,
2011c).

At the inconclusive reactor retest: at this test, the bTB reactor incidence among SIR animals was almost
two times that of the national rate (Clegg et al., 2011c).

Following a negative inconclusive retest result (so-called ‘transient SIRs’, TIRs)
a. Following movement to another herd: 3.44% of the SIR animals that moved from the
herd within 6 months of a clear retest were positive at the next test/slaughter, compared
to 0.26% of the SICTT –ve cohort animals (Clegg et al., 2011c).
b. If remaining in the same herd: for TIRs that remained in the herd of disclosure, the time
to diagnosis with bTB for TIRs was on average 78% shorter than for non-TIR animals
(Clegg et al., 2011b).

At most of these testing opportunities, the past history of the animal could not have influenced
interpretation of the test result.

In broad terms, a S/TIR could be either a non-infected animal returning a suspect result, often following
exposure to environmental or other mycobacteria, or a bTB infected animal returning a suspect, rather
than a positive, SICTT result, due to a broad range of factors that relate to the animal, such as co-infection with
or exposure to other mycobacteria, the tuberculin and/or the method of administration (de la Rua-
Domenech et al., 2006). The results from this study clearly highlight the presence of the latter, with S/TIRs
having a higher risk of being declared bTB positive at each future testing opportunity, compared to SICTT
–ve cohort animals from the same herds. Consequently, differential treatment of S/TIR animals is justified.

3.2.3 The importance of wildlife in bTB persistence

There has been an increasing understanding about the role played by badgers in the epidemiology of bTB in
cattle in Ireland. There is little doubt that badgers are a maintenance host with spillback to cattle –
essentially, an upstream driver of infection (More, 2009). Substantial supporting evidence is now available.

Infection with M. bovis is endemic in Irish badgers (Murphy et al., 2010, 2011), however, prevalence is not
uniform throughout the country (Furphy et al., 2012). There appears to be no geographic clustering of strain
types associated with prevalence (Furphy et al., 2012). In areas where cattle are at high bTB risk, M. bovis
prevalence in badgers is high: 36.3% using enhanced post mortem examination and bacteriological culture
(but only 12.1% based on confirmed gross visible lesion detection alone) (Murphy et al., 2010). In areas
where bTB prevalence in cattle is very low or absent, infection is still present in badgers, albeit at lower
levels. Based on a recent ‘greenfield’ study, M. bovis infection was identified in 14.9% of the badgers using
equivalent enhanced methods (but with a higher concentration of decontaminant) in areas of Ireland with
historical low bTB herd prevalence, and very little opportunity over many years for cattle to badger
transmission (Murphy et al., 2011). Corner et al. (2011) suggest that badger social structures and the
longevity of infected animals make them an ideal maintenance host for M. bovis infection.
Results from two large field trials (the east Offaly trial, Eves, 1999, Ó Máirtín et al., 1998a,b; the four area trial, Griffín et al., 2005) provide consistent and conclusive evidence of spillover of infection from badgers to cattle. A significant fall in bTB prevalence in cattle was observed in both trials in areas where badgers were proactively removed, in comparison to control areas. Further, these differences have been sustained for prolonged periods subsequently, in the removal areas of both the east Offaly (Kelly et al., 2008) and four area (Byrne et al., 2014) projects. Relative to reactive culling, proactive badger culling in the east Offaly area was associated with a decrease in herd bTB incidence during the periods of both intensive (1989-95) and less-intensive (1996-2004) badger removal. By 2004, significant decreases of 22% and 37% were observed in the entire and the inner proactive removal areas, respectively, with the size of this decrease increasing with time (Kelly et al., 2008). During 2007-12 (5-10 years after the end of the four area project), herds within the former removal area had 0.53 the odds of a herd bTB restriction in any given year than a herd within the former reference area (Byrne et al., 2014).

Since 2004, Ireland has implemented a national programme of badger culling, specifically to reduce badger density in areas with chronic problems of bTB in cattle herds (Sheridan, 2011; Byrne et al., 2013). It seeks to facilitate the business of farming in tandem with the conservation of a healthy national badger population (Sheridan, 2011). This strategy, which forms part of national bTB eradication programme, draws on the experience of the east Offaly and four area projects (but noting that these trials did not explicitly evaluate different culling methods), and on key principles of infectious disease epidemiology, including control. Culling is initially conducted reactively (in response to cattle bTB breakdowns) then continued proactively, covering areas up to 2 km beyond the farm boundary (Byrne et al., 2013), leading to a significant reduction in badger density (Byrne et al., 2013) and changes to the spatial organisation and activity of badgers (O’Corry-Crowe et al., 1996). In contrast to the experience elsewhere (More et al., 2007), adverse effects on infection prevalence following focused badger removal have not been observed in Ireland, either in cattle (Griffin et al., 2005; Kelly et al., 2008; Olea-Popolka et al., 2009) or in badgers (Corner et al., 2008a). During the four area project, there was an overall long term decrease in the prevalence of bTB in the re-emergent badger population in proactively culled areas, and no consistent trend in reactively culled areas (Corner et al., 2008a). Subsequently, there has been a substantial fall in bTB prevalence in badgers captured as part of the national programme during 2009-12 (Byrne et al., in preparation).

Olea-Popolka et al. (2009) investigated the impact of targeted badger removal on the survival time to future bTB episodes in herds in and around areas where badgers were removed in county Laois, during 1989 to 2004. The authors conducted a survival analysis, with the main exposure in this study being the geographical location of herds relative to the area in which targeted badger removal was conducted, that is:

- Group 0: Reference (unexposed) herds, more than 500m from an index herd (or any associated parcels) at the time of a bTB breakdown
- Group 1: Index herds
- Group 2: Herds <25 m from an index herd or any associated parcels (immediate neighbours)
- Group 3: Herds 25-150 m distant
- Group 4: Herds 150-500 m distant

Herd in areas around targeted badger removal (groups 2-4) had significantly longer survival times to future bTB episodes compared with herds outside these areas (group 0). Further, the future bTB risk in index herds (group 1) was no different to those in reference herds (group 0). Because group 1 herds are traditionally at greater risk of a future herd breakdown (for example, Olea-Popolka et al., 2004), these results suggest a beneficial impact of targeted removal on their survival time. Several aspects of the study design may lead to bias (more effective bTB control in cattle herds in Co. Laois compared with other counties, erroneous inclusion of some index herds where badger removal had not taken place, insufficient control of herd fragmentation), however, in each case, the effect will be towards the null. Overall, the study suggests that targeted badger removal had a beneficial effect on the survival time to future bTB episodes in herds in and around areas where badgers were removed.

Efforts towards development of a bTB vaccine for badgers using BCG (Bacillus Calmette-Guérin) have been described in detail elsewhere (Sheridan, 2011; Robinson et al., 2012). Briefly, a range of pen-based experiments have highlighted a protective effect in badgers to artificial bTB challenge using both the subcutaneous and mucosal routes of administration (Corner et al., 2007, 2008b,c; Lesellier et al., 2009). Issues relating to licensing (Murphy et al., 2008) and delivery (Kelly et al., 2011) have also been considered. A field trial was subsequently conducted over three zones covering approximately 755 km² in Co. Kilkenny (Corner et al., 2009; Aznar et al., 2011), and analyses are now underway, focusing on incidence (Aznar et al., 2013; Aznar et al., 2014) and prevalence data. A non-inferiority trial, comparing
badger vaccination and culling, is currently being conducted in 6 counties in Ireland (J. O’Keeffe, pers. comm.).

3.2.4 The importance of cattle introductions in bTB persistence

In contrast to bTB establishment, it is unlikely that introduced animals are contributing to the observed pattern of bTB persistence in Ireland (that is, a bias towards herds with a previous history of bTB infection, thereby leading to infection that is clustered in both space and time). This would only be possible if the movement of infected animals were substantially biased towards herds with a known bTB history. Rather, it would be expected that introduced infection would lead to a relatively dispersed spatial pattern of infection (Kelly and More, 2011).

3.3 Local persistence: disentangling relative importance

White et al. (2013) describe the first work in Ireland to disentangle the various infection sources, and determine their relative importance. In this work, the authors specifically focus on the relative importance of ‘neighbourhood’, specifically farm-to-farm spread and spread from wildlife, in bTB persistence. A case-control study was conducted of Irish herds that did (the index herds) and did not experience a bTB episode during 2006. A multivariable model was developed incorporating a broad range of independent variables, related to both the index herd (herd history, herd size, number of animals purchased) and to neighbouring herds (zone 1: herds within 25 m; zone 2: herds between 26 and 150 m; zone 3: herds between 151 and 1000 m). In the study population, ~43% of bTB episodes in 2006 could be attributed to the bTB history in the index and neighbouring herds during the previous 2 years. The population attributable fraction of various infection sources were as follows:

- 15% to the bTB history of the index herd during 2001-05;
- 20% to the bTB history of neighbouring herds that were directly contiguous (≤25 m) during 2004-05;
- 19% to the bTB history of neighbouring herds that were not directly contiguous (>25 m) during 2005.

Logically, contiguous spread will be limited to directly contiguous herds, whereas wildlife spread is not limited by contiguity. On this basis, the authors attribute 15% of the bTB episodes in the study to residual infection, between 0-20% to contiguous spread, and between 19-39% to wildlife. The relative value of these results is of particular interest, noting that other factors (some modeled: herd size, animals purchased; some currently not accounted for in the model) also contribute to future bTB risk. As noted by White et al. (2013), it would be useful to repeat these analyses in areas of the country where badger-to-cattle transmission is likely to have been minimised, such as within the areas of the four area project (Griffin et al., 2005) subjected to proactive badger removal. This would allow a better estimate of true cattle-to-cattle (herd-to-herd) spread among herds directly contiguous to one-another.

4. Managing bTB risk

Detailed information about the Irish bTB eradication programme has been presented previously, including policy changes, programme supports including data management systems, the wildlife disease control strategy, the use of diagnostics and quality control (More and Good, 2006; Sheridan, 2011; Duignan et al., 2012). The national programme handbook is available online (Good et al., 2010).

In recent years, there have been three primary drivers for policy change: scientific advances, ongoing improvements to programme supports, and ongoing programme review. We will consider only the first two here. Following the work of Clegg et al. (2011b,c), policy changes were introduced in 2012 to confine inconclusive reactors to the herd of origin with a life-long movement restriction, except direct to slaughter. Drawing on the work of White et al. (2013), increased controls (testing, restrictions) have been placed on herds contiguous to high-risk bTB breakdowns. Ongoing technical improvements are also facilitating programme management. The national Animal Health Computer System (AHCS, a bespoke web-based management system for the Irish bTB eradication programme, fully operational since early 2005) has been specifically programmed to manage all aspects of the bTB eradication programme, thereby ensuring compliance with EU and national legislation and consistent application across the country. AHCS is closely integrated with the Animal Identification and Movement (AIM) system, allowing consistent application of both herd- and animal-based controls.
5. Evaluating national progress

An objective assessment of the national bTB situation in Ireland has become increasingly important, to allow critical evaluation of progress towards control and eradication. A number of performance measurements are routinely available (including bTB herd incidence, reactor animals per thousand tests [APT] and number of reactors removed), each highlighting a steadily improving situation. These trends are mirrored in a recent time-series analysis of restriction rates to the annual surveillance test in low risk herds (Gallagher et al., in preparation). Greater detail is increasingly available about defined aspects of the programme, including activities relating to surveillance and to control. Concerns about the effectiveness of abattoir surveillance have been identified (Frankena et al., 2007), including substantial between-abattoir variation during 2003-04 with respect to both submission risk (the number of animals submitted with lesions divided by the number of attested animals killed) and confirmation risk (the number of animals with laboratory confirmed lesions divided by the number of animals submitted with lesions). At this time, there was a 9-fold difference in submission risk between abattoirs submitted lesions from at least 10 animals (range 7 to 65 per 10,000, average 22 per 10,000). Collins (1997) suggests that variations in factory surveillance efficiency may be due to factory-related circumstances, for example, line speed and light intensity, and/or to factors related to the veterinary inspector, for example, their experience, interest, motivation and workload. In a later study, using equivalent data from 2005-07, improvement was evident, including an observed 5-fold difference in submission risk between abattoirs (range 11 to 58 per 10,000, average 25 per 10,000; Olea-Popelka et al., 2012). Since 2006 the national TB-suspect lesion submission rate has risen from 26.8/10,000 animals slaughtered to 37/10,000 in 2012 while over the same period the M.bovis confirmation rate has fallen from 18.2/10,000 to 14.9/10,000 animals slaughtered. Clegg et al. (in preparation) found evidence of improvement in testing effectiveness among private veterinary practitioners in 2011 compared with 2008 in a range of indices, which is likely attributable to programme quality control (Duignan et al., 2012). Herd recurrence remains problematic, with approximately 12% positive at the post-derestriction test (Abernethy et al., 2013). Nonetheless, there has been clear evidence of improvement, with 2008-derestricted herds being 0.74 times (95% confidence interval: 0.68–0.81) as likely to be restricted in the 3 years following derestriction compared with 1998-derestricted herds (Gallagher et al., 2013). McGrath et al. (2014) highlighted spatial changes in annual animal-level bTB incidence during 2008 to 2012 in comparison with the mean annual bTB incidence during 1998 to 2007, highlighting general improvement in latter periods.

6. Future challenges

6.1 How much additional effort is needed?

During the last 15 or so years, epidemiological research in Ireland has primarily focused on an improved understanding of bTB risk. This information has progressively been translated into substantial policy changes leading to measurable improvement in both surveillance (detecting infection in herds and animals) and control (clearing infection from herds, once detected). bTB is now under good control (Abernethy et al., 2013; Gallagher et al., 2013). It is clear, however, that final eradication will not be achievable with existing surveillance and control tools. In particular, we are not yet able to adequately limit ongoing infection from badgers, an upstream driver of infection in Ireland. In response, current research is primarily focused on two key areas: the potential of additional measures to further limit cattle-to-cattle transmission, and sustainable methods to limit badger-to-cattle transmission, in particular a bTB vaccine for badgers. Progress with the former will lead to a further drop in herd bTB incidence in Ireland, but not to the point of eradication. Critical information about the latter will become available shortly, based on results from the Kilkenny badger vaccination field trial (Sheridan, 2011; Aznar et al., 2011, 2013, 2014). A non-inferiority trial is currently being conducted in six counties in Ireland evaluating the relative impacts of badger culling and vaccination on herd-level bTB prevalence (J. O’Keeffe, pers. comm.).

The next logical question to be asked concerns the additional effort that will be required, to move towards final eradication. In terms of efforts to limit badger-to-cattle transmission, some key questions include: will ongoing culling be required?, how effective does badger vaccine need to be, in terms of efficacy (efficacy for infectiousness, efficacy for susceptibility)?, what level of vaccine coverage will be needed?, and will ongoing culling be required? In terms of efforts to limit cattle-to-cattle transmission, we need to know what, if any, additional controls will be required, over and above those already in place? These issues are currently being explored, based on calculations of the reproduction ratio of both the overall system and of its component parts (badger-to-badger, cattle-to-cattle, and interactions), given the current situation and under a range of control scenarios (Aznar et al., in preparation).
6.2 False positive reactors

A percentage of non-infected animals are falsely positive to current testing methods. This is an ongoing challenge, given the imperfect specificity of test methods (including the single intradermal comparative tuberculin test (SICTT) and interferon-γ assay), but will become more so, as the positive predictive value falls with reducing bTB prevalence.

The specificity of the SICTT has been estimated to be 99.5% (median, ranging from 78.8-100%) based on international studies in cattle populations free of bTB (de la Rua-Domenech et al., 2006), and 99.2-99.8% using latent class analysis on Irish samples without a gold standard (Clegg et al., 2011a). Non-specific reactors can occur following exposure to non-pathogenic environmental mycobacterial species (Gormley et al., 2013), including *M. hiberniae* (Cooney et al., 1997). The interferon-γ assay, with lower specificity, is primarily used in conjunction with the SICTT in severely infected herds or in groups of animals where the reduced specificity is considered acceptable (Gormley et al., 2013). Estimates of the specificity of the assay include 88.1-96.6% (depending on the cut-off used, Monaghan et al., 1997), 96.6% (median, de la Rua-Domenech et al., 2006), and 86.8-89.4% (Clegg et al., 2011a).

Ireland has operated a ‘Singleton Protocol’ since 1996, allowing the early restoration of disease-free status to herds with a single reactor, where bTB is not confirmed by epidemiological investigation, by postmortem examination or by further test (Good et al., 2010). Murray et al. (2012) evaluated the ability of the Protocol to identify false positive reactors, by comparing the animal lesion rate at slaughter and reactor retest breakdown rate in single reactor breakdowns, including those that were and were not eligible under this Protocol. Significant differences were observed in animal lesion rate but not reactor retest breakdown rate, highlighting the value of the Protocol, but also the potential for improvement in the classification used. Wolfe et al. (2010) has previously highlighted difficulties in the development of predictive statistical models for recurrence.

An improved understanding of risk factors for false positive results will assist with local decision-making. Gormley et al. (2013) used cohorts of animals from low prevalence tuberculosis herds to assess a range of risk factors that might influence the specificity of the interferon-γ assay. Risk factors for false positive results include animal age (with risk increasing with age) and region of herd origin. Of note, a high proportion of herds with multiple interferon-γ assay positive animals were located in one county, with evidence of within-herd clustering, suggesting a localised source of non-specific sensitization (Gormley et al., 2013). Forthcoming work is anticipated on the impact of proximity to peat land on SICTT performance, and on animals with SICTT responses at an otherwise clear herd test. Collectively, this information may assist in allowing test performance to be optimised, in order to reduce the disclosure rate of false positive reactors (Gormley et al., 2013). There has also been ongoing work to investigate the changing characteristics of bTB episodes (J. O’Keeffe, pers. comm.), providing further insights into the relative importance of false positive reactors in the Irish programme.

6.3 Re-engagement with the farming community

During 1988-92, a new executive agency, ERAD, was created, with the task to provide more dynamic management of the programme and to reduce disease levels by half within a four-year time frame. Stakeholder ownership was important during this period, but has become much less prominent subsequently. Although there is a good case for government involvement (badgers as a protected species, the benefit from collective action in the eradication of this infectious disease, Devitt et al., 2013), industry is the main beneficiary of bTB control in Ireland. However, all aspects of programme governance are currently directed and delivered by government, and the contribution of industry to key aspects of governance, including policy formulation and programme management, is minimal (More, 2009). As highlighted by Sheridan (2011), a programme re-launch will be needed, once all critical constraints to eradication have been addressed. From this time, it will be important that stakeholders once again play a much greater role in programme ownership.

7. Conclusions

In conclusion, there is close interaction between science and policy in Ireland, seeking both to understand and effectively manage bTB risk. Substantial national progress is being made, and herd- and animal-level prevalence is falling. There has been substantial recent progress in the development of strategies to
adequately limit ongoing infection from wildlife; if successful, it may soon to possible to address the remaining constraints to eradication. Substantial challenges remain, but there is a sound basis for considerable optimism.

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9. References


